UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2025

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM TO**

Commission File Number 001-33672

PALISADE BIO, INC.

(Exact name of Registrant as specified in its Charter)

Delaware	**52-2007292**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
4600 South Syracuse Street, Suite 900 Denver, Colorado[1]	**80237**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (858) 704-4900

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
common stock, $0.01 par value	PALI	Nasdaq Capital Market

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐ NO ☒

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). YES ☒ NO ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

The aggregate market value of the common stock held by non-affiliates of the registrant, based on the closing price of a share of the registrant's common stock on June 30, 2025 as reported by the Nasdaq Capital Market on such date, was approximately $11.2 million. Shares of common stock held by each executive officer and director and by each other person who may be deemed to be an affiliate of the registrant, have been excluded from this computation. The determination of affiliate status for this purpose is not necessarily a conclusive determination for other purposes.

As of March 18, 2026, the registrant had 165,884,817 shares of common stock, $0.01 par value per share, outstanding.

[1] The Company does not currently maintain a physical headquarters but maintains a mailing address at 4600 South Syracuse Street, Suite 900, Denver, Colorado, 80237

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement relating to the 2026 Annual Meeting of Stockholders are incorporated herein by reference in Part III of this Annual Report on Form 10-K to the extent stated herein. The proxy statement will be filed with the Securities and Exchange Commission within 120 days of the registrant's fiscal year ended December 31, 2025.

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Cautionary Note Regarding Forward-Looking Statements and Risk Factor Summary

This Annual Report on Form 10-K, including "Management's Discussion and Analysis of Financial Condition and Results of Operations," contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended, (the "Exchange Act"). These statements relate to future events or to our future operating or financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. Some of these factors are more fully discussed in Section 1A of this Annual Report on Form 10-K entitled "Risk Factors" and elsewhere herein.

Forward-looking statements may include, but are not limited to, statements about:

- *the results of our preclinical and clinical trials;*
- *our clinical trial plans and timelines;*
- *estimates about the size and growth potential of the markets for our product candidates, and our ability to serve those markets, including any potential revenue generated;*
- *future regulatory, judicial, and legislative changes or developments in the United States ("U.S.") and foreign countries and the impact of these changes;*
- *our ability to successfully develop our licensed technologies;*
- *our ability to build a commercial infrastructure in the U.S. and other markets;*
- *our ability to compete effectively in a competitive industry;*
- *our ability to identify and qualify additional manufacturers to provide active pharmaceutical ingredients ("API") and manufacture drug product;*
- *our ability to enter into commercial supply agreements;*
- *the success of competing technologies that are or may become available;*
- *our ability to attract and retain key scientific or management personnel;*
- *the accuracy of our estimates regarding expenses, capital requirements and needs for additional financing;*
- *our ability to obtain funding for our operations; and*
- *our ability to attract collaborators and strategic partners.*

In some cases, you can identify forward-looking statements by terms such as "may," "will," "intend," "should," "could," "would," "expects," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "potential" and similar expressions intended to identify forward-looking statements. There can be no assurance that any of the events anticipated by forward-looking statements will occur or, if any of them do occur, what impact they will have on our business, results of operations and financial condition. You should not rely on forward-looking statements as predictions of future events. The outcome of the events described in these forward-looking statements is subject to risks, uncertainties, assumptions, and other factors described in Part I, Item 1A Risk Factors and elsewhere in this Annual Report on Form 10-K. Moreover, we operate in a very competitive and rapidly changing environment. New risks and uncertainties may emerge from time to time, and it is not possible for us to predict all risks and uncertainties that could have an impact on any forward-looking statements contained in this Annual Report on Form 10-K. These statements reflect our current views with respect to future events and are based on assumptions and are subject to risks and uncertainties. As such, our actual results may differ significantly from those expressed in any forward-looking statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements.

Also, these forward-looking statements represent our estimates and assumptions only as of the date of the document containing the applicable statement. Except as required by law, we undertake no obligation to update or revise any forward-looking statements to reflect new information or future events or developments. Thus, you should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements. You should read this Annual Report on Form 10-K, together with the documents that we have previously filed with the Securities and Exchange Commission ("SEC") completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all the forward-looking statements in the foregoing documents by these cautionary statements.

RISK FACTOR SUMMARY

We face many risks and uncertainties, as more fully described in this Annual Report on Form 10-K under the heading "Risk Factors." The summary below does not contain all the information that may be important to you, and you should read this summary together with the more detailed discussion of these risks and uncertainties contained in "Risk Factors."

Risks Related to Our Development, Commercialization and Regulatory Approval of Our Product Candidates

- Our business depends on the successful clinical development, regulatory approval, and commercialization of our lead asset PALI-2108.
- There are substantial risks in drug development, and, as a result, we may not be able to successfully develop any product candidate, including our lead clinical product candidate, PALI-2108.
- We depend on our license agreement with Giiant Pharma Inc. ("Giiant") to permit us to use patents and patent applications relating to PALI-2108. Termination of these rights or the failure to comply with our obligations under the license agreement could materially harm our business and prevent us from developing or commercializing PALI-2108, our lead clinical product candidate.
- We are currently conducting a Phase 1 clinical trial of PALI-2108 in Canada, and the U.S. Food and Drug Administration ("FDA") or applicable foreign regulatory authorities may not accept data from such trials, or any other trial we conduct outside of the U.S.
- We may find it difficult to enroll patients in our clinical trials, which could delay or prevent us from proceeding with clinical trials of our product candidates.
- We expect that our operations and development of PALI-2108 will require more capital than we currently have, and we cannot guarantee when or if we will be able to secure such additional funding.
- Our product candidates, including our lead clinical product candidate PALI-2108, may cause undesirable side effects or have other unexpected properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in post-approval regulatory action.
- There can be no assurance that our product candidates will obtain regulatory approval.
- If clinical studies of PALI-2108 do not yield successful results, we may discontinue the development of PALI-2108.
- It may take us longer than we estimate to complete clinical trials, and we may not be able to complete them at all.

Risks Related to Healthcare Laws and Other Legal Compliance Matters

- Recent and future changes in healthcare legislation and regulations may increase the difficulty and cost to obtain marketing approval for a drug candidate, increase the costs to commercialize an approved product, and adversely affect the price set for such product.
- Our business operations and current and future relationships with contractors, investigators, healthcare professionals, consultants, third-party payors, patient organizations, customers, and others will be subject to applicable healthcare regulatory laws, which could expose us to penalties.

Risks Related to Our Business

- We have a limited operating history and have never generated any revenues from product sales.
- Our business model assumes revenue from, among other activities, marketing or out-licensing the products we develop. PALI-2108 is in the early stages of clinical development, and because we have a short development history with PALI-2108, there is a limited amount of information about us upon which you can evaluate our business and prospects.
- We may choose to discontinue the development or commercialization of any of our product candidates, or may choose not to commercialize product candidates in approved indications, at any time during development or after approval, which could adversely affect us and our operations.
- Our inability to successfully in-license, acquire, develop and market additional product candidates or approved products could impair our ability to grow our business.
- Changes in funding for the FDA and other government agencies or comparable foreign regulatory authorities could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent these agencies or authorities from performing normal business functions on which the operations of our business may rely, which could negatively impact our business.

Risks Related to Our Dependence on Third Parties

- We currently rely on and we intend to continue to rely on third-party Contract Research Organizations ("CROs") and other third parties to conduct and oversee our clinical trials. If these third parties do not meet our requirements or otherwise conduct the trials as required, we may not be able to satisfy our contractual obligations for, obtain regulatory approval for, or commercialize our product candidates.
- We depend on two qualified suppliers for the active pharmaceutical ingredient used in the clinical trials of PALI-2108. Insufficient availability of the API or other raw materials necessary to manufacture PALI-2108, or the inability of our suppliers to manufacture and supply our products on commercially reasonable terms, could adversely impact our business, results of operations and financial condition.
- We expect to rely on collaborations with third parties for the successful development and commercialization of our product candidates.
- We currently rely on third-party contractors to supply, manufacture and distribute clinical drug supplies for our product candidates.

Risks Related to Our Financial Operations

- We have a history of net operating losses, and we expect to continue to incur net operating losses and may never achieve profitability.
- Failure to remediate a material weakness in internal controls over financial reporting could result in material misstatements in our consolidated financial statements.

Risks Related to Our Intellectual Property

- We may not be able to obtain, maintain or enforce global patent rights or other intellectual property rights that cover our product candidates and technologies that are of sufficient breadth to prevent third parties from competing against us.
- If we fail to comply with our obligations under our intellectual property license agreements, we could lose license rights that are important to our business.

PART I

As used in this Annual Report on Form 10-K, unless the context indicates or otherwise requires, “Palisade,” “Palisade Bio,” the "Company,” “we,” “us,” and “our” or similar designations refer to Palisade Bio, Inc., a Delaware corporation, and its subsidiaries. Any reference to “common shares” or “common stock,” refers to our $0.01 par value common stock. Any reference to “Series A Preferred Stock” refers to our Series A 4.5% Convertible Preferred Stock. Any reference to “Leading Biosciences, Inc.” or “LBS” refers to our operations prior to the completion of our merger with Seneca Biopharma, Inc. ("Seneca") on April 27, 2021 (the "Seneca Merger"). Any technology that we currently own or may acquire the rights to in the future is referred to by us as either a “product candidate” or "product candidates." Additionally, any reference herein that refers to preclinical studies also refers to nonclinical studies.

Item 1. Business.

Company Overview

We are a clinical-stage biopharmaceutical company developing next-generation, once-daily, oral phosphodiesterase-4 (“PDE4”) inhibitor prodrugs designed for targeted delivery to the terminal ileum and colon. Our lead clinical product candidate, PALI-2108, is being developed as a treatment for patients living with inflammatory bowel disease (“IBD”), including ulcerative colitis (“UC”) and Crohn’s disease (“CD”).

Our Strategy

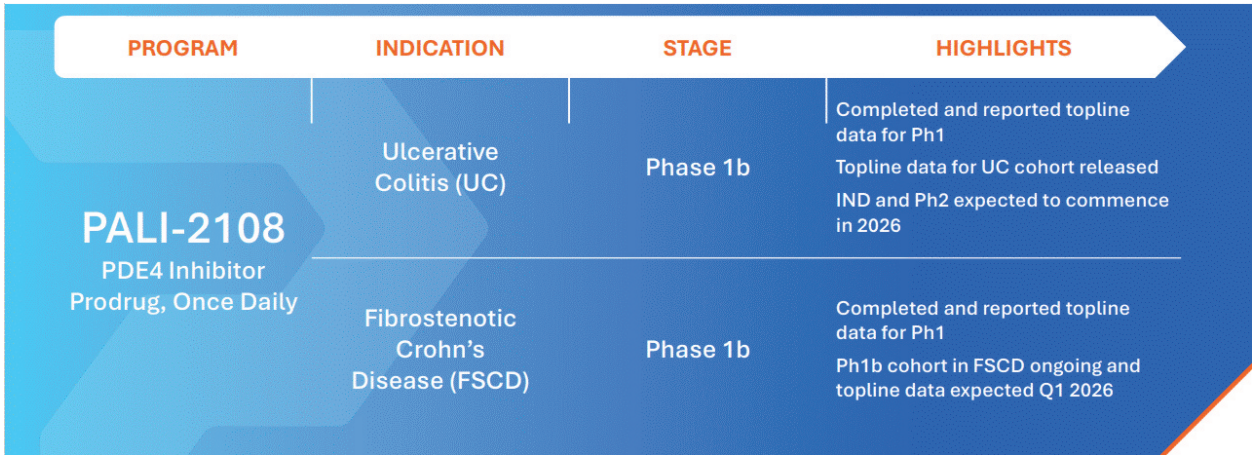
We are committed to advancing a next generation of once daily, oral PDE4 inhibitor prodrugs to improve pharmacology, tolerability and convenience for patients with inflammatory and fibrotic diseases.

We believe the key elements of our strategy include:

- advancing our lead clinical product candidate, PALI-2108, towards a Phase 2 clinical study in UC designed to evaluate clinical remission response and pharmacodynamic biomarkers over 12 weeks, with an extension phase assessing maintenance of remission;
- the completion of early studies in FSCD to further characterize PALI-2108's safety, pharmacology and potential therapeutic benefit across inflammatory bowel disease indications;
- leveraging our drug development platform infrastructure to identify product candidates that target inflammatory and fibrotic diseases;
- pursuing strategic partnerships to further expand our programs and maximize the worldwide potential of our product candidates and platform; and
- pursuing in-licensing/acquisitions of new product candidates or out-licensing/sales of our existing product candidates.

Our Pipeline

We are currently advancing clinical trials of PALI-2108 for the treatment of IBD, including UC and CD. The following table summarizes the current stages of our clinical and research programs:



Our Precision Medicine Approach

We are developing a biomarker-based patient selection approach that we believe may aid clinicians in identifying patients who may better respond to PALI-2108, thereby improving the rate of clinical response previously demonstrated with PDE4 inhibitors. Our approach involves the use of clinical and multiomics data from large patient populations to identify PDE4-related biomarkers that are correlated with IBD, its severity, and which are modified with local PDE4-inhibitor therapy in the colon. Based on our research, we have initiated the development of corresponding biomarker assays for these PDE4-related biomarkers that we expect to use in our current and future clinical studies with the aim of developing regulatory approved tests for selecting potential responders to PALI-2108.

PALI-2108

Our lead clinical product candidate, PALI-2108, is a once-daily, oral prodrug designed for targeted delivery of PDE4 inhibition to the terminal ileum and colon through local bacterial bioactivation. The prodrug is pharmacologically inactive until it reaches the lower intestine, where bacterial enzymes convert it into the active PDE4 inhibitor at sites of inflammation and fibrosis. This targeted activation strategy prevents absorption in the upper gut, enables sustained local exposure with controlled systemic distribution, and is engineered to reduce peak plasma levels, thereby improving the overall therapeutic index and reducing tolerability limitations such as diarrhea, nausea and headache that have constrained systemic PDE4 inhibitors.

With a glucuronic-derived sugar moiety, PALI-2108 remains minimally absorbed until activated by the colonic bacterium enzyme β-glucuronidase. We believe that localized bioactivation may help focus the effects of PALI-2108 where it would be most beneficial to a patient suffering from IBD.

PALI-2108 for UC

In UC mouse models, we have demonstrated the dose-dependent efficacy of PALI-2108. Specifically, we utilized Dextran Sodium Sulfate ("DSS")-induced UC mouse models and target engagement in oxazolone-induced colitis. Thus, based on the research conducted on these mouse models, we demonstrated that PALI-2108 has preferential colon activation. This preferential colon activation offers a unique approach to delivering the PDE4 inhibitor locally within the colon. The local bioactivation of PALI-2108 prodrug is designed to prevent the systemic toxicity inherent with immunosuppression and avoid the known tolerability issues of PDE4 inhibitors.

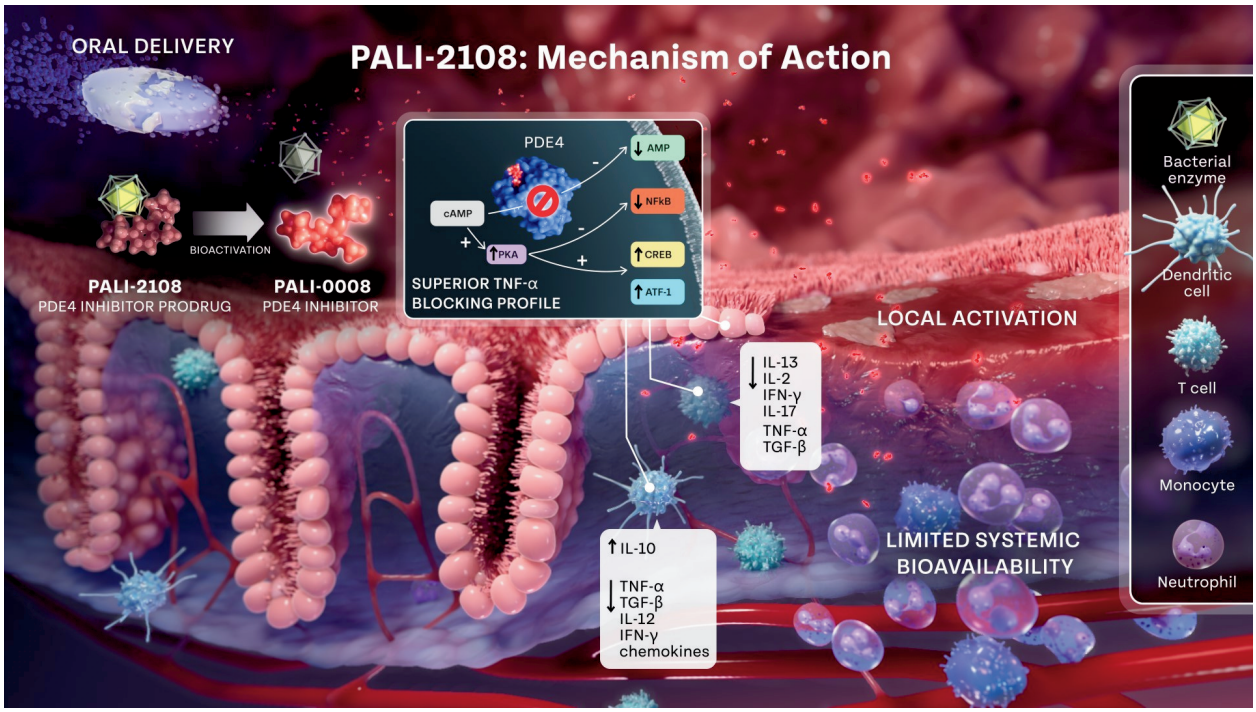
PALI-2108 for FSCD

Studies have shown that patients with intestinal fibrosis exhibit elevated PDE4 B and D enzyme levels in intestinal tissues. Also, preclinical research using a chronic DSS-induced mouse model of intestinal fibrosis shows similarly

decreased PDE4 enzyme levels and demonstrated that systemic administration of PDE4 inhibitors improve clinical symptoms and reduce known biomarkers of fibrosis associated with FSCD. In these studies, systemically delivered PDE4 inhibitors significantly improved clinical outcomes, including body weight, disease activity, colon length, and key biomarkers of intestinal fibrosis, such as α-SMA and MMPs, with these markers returning to baseline levels upon treatment. Additionally, PDE4 inhibition was found to prevent the breakdown of cAMP, which in turn inhibits fibroblast functions, including tissue remodeling. Further research indicates that TGF-beta, a key driver of fibrosis, modulates cAMP levels, and PDE4 inhibition exerts particularly strong anti-fibrotic effects when TGF-beta-induced fibroblast stimulation is present.

We conducted a study evaluating the anti-inflammatory and anti-fibrotic effects of PALI-2108, a locally bioactivated PDE4 inhibitor, in an acute DSS-induced mouse model. Treatment with PALI-2108 resulted in dose-dependent improvements in clinical outcomes, including disease activity and colon length. Additionally, PDE4B expression in colon tissues was reduced in a dose-dependent manner, intracellular cAMP levels increased, and TNF-alpha levels in colon tissues were normalized in most of the mice treated.

Bioinformatics analysis of colon biopsy gene expression data (RNA-seq) further supports the effects of PALI-2108. The analysis reveals a dose-dependent modulation of 187 genes associated with four major fibrotic pathways in IBD. Furthermore, the treatment shows a dose-dependent improvement in fibrosis enrichment scores for FSCD markers. These findings suggest that PALI-2108 is a promising dual-acting drug candidate, with both anti-inflammatory and anti-fibrotic properties, for the treatment of FSCD.



Phase 1 Clinical Study of PALI-2108

The Phase 1 clinical study of PALI-2108 is a single-center, randomized, double-blinded, placebo-controlled clinical study focused on safety, tolerability, and pharmacokinetics ("PK") in both healthy volunteers and UC patients. The clinical study included an open-label UC patient cohort with multiple dosing arms in which we will evaluate the pharmacodynamics ("PD") of PALI-2108 in healthy volunteers.

On October 9, 2024, Health Canada issued a No Objection Letter for our Phase 1 human clinical study of PALI-2108 for the treatment of UC. We officially began the study on November 7, 2024. We have completed the dosing of 89 subjects across all planned cohorts of the study. Each of the five Single Ascending Dose ("SAD") cohorts and the four Multiple Ascending Dose ("MAD") cohorts consisted of eight subjects, with six subjects receiving the drug and two subjects receiving a placebo. The food effects ("FE") study included two cohorts each of six subjects, of

which one cohort was in a fasted state and the other cohort in a fed state. Finally, we have completed the dosing of all five UC patients in the UC cohort of the study.

On May 27, 2025, we announced positive results from the SAD, MAD and FE cohorts in healthy volunteers and on August 7, 2025 and September 17, 2025, we announced positive results from the UC cohort portion of the study. The clinical study successfully met its primary endpoints of safety, tolerability, and PK. Although the results are preliminary and require validation in randomized, controlled trials, we also reported that the patients included in the UC cohort demonstrated rapid and consistent clinical activity, with all five of the patients responding to treatment.

On October 16, 2025, we dosed our first patients in an exploratory Phase 1b cohort in FSCD while we complete longer-term chronic safety and toxicology studies. The exploratory Phase 1b cohort in FSCD will evaluate the safety, tolerability, PK, and PD of once-daily oral dosing of PALI-2108 over a 14-day treatment period as well as evaluate tissue-level pharmacology and molecular responses using paired ileal biopsies and peripheral blood mononuclear cells. Analyses will include single-nucleus and single-cell RNA sequencing to characterize treatment-induced changes in inflammatory and fibrotic signaling. Exploratory endpoints include endoscopic and histologic measures to assess structural and inflammatory features of FSCD lesions.

The exploratory Phase 1b cohort in FSCD is expected to be followed by the initiation of Phase 2 clinical programs to assess PALI-2108's efficacy, safety, and tolerability in patients with moderate to severe UC, as well as those with CD.

Planned Clinical Trial in the United States

In addition to conducting clinical studies in Canada, we anticipate data from the exploratory Phase 1b cohort in FSCD together with results from the Phase 1/1b UC program will support Investigational New Drug Application ("IND") submissions to the FDA for a Phase 2 UC study in the second quarter of 2026 and a Phase 2 CD study in the second half of 2026.

Market

We are advancing next-generation oral PDE4 inhibitor prodrugs designed to improve pharmacology, tolerability and convenience for patients with inflammatory and fibrotic diseases, which we believe will address a large, well-established need among patients living with inflammatory and fibrotic diseases.

Our initial indications for PALI-2108 are:

Ulcerative Colitis

UC is a chronic IBD that primarily affects the colon and rectum, leading to long-lasting inflammation and ulcers in the digestive tract. Common symptoms include abdominal pain, diarrhea, and rectal bleeding. The prevalence of UC is estimated to range from 156 to 291 cases per 100,000 people globally. In the eight major markets ("8MM"), diagnosed incident cases of UC are projected to increase from 160,122 cases in 2021 to 168,467 cases by 2031, reflecting an annual growth rate ("AGR") of 0.52%. The U.S. is expected to have the highest number of diagnosed incident cases in 2031, totaling 104,795, while France will have the fewest at 2,972 cases. Additionally, diagnosed prevalent cases are anticipated to rise from 1,946,428 in 2021 to 2,069,770 in 2031, with an AGR of 0.63%. The U.S. is again projected to lead in prevalence in 2031 with 655,317 cases, whereas Canada is projected to report the lowest with 91,186 cases. This growth in diagnosed cases is largely attributed to changes in population dynamics across these markets. The market for 8MM for UC treatments was valued at approximately $7.3 billion in 2021 and is expected to grow to over $9.5 billion in 2031 at a compound annual growth rate ("CAGR") of approximately 2.78%. Market expansion is driven by the increasing prevalence of the disease, advancements in diagnostic techniques, and the development of more effective and targeted therapies.

Crohn's Disease

CD is an IBD that can affect any part of the gastrointestinal tract, from the mouth to the anus. It is characterized by inflammation that can penetrate deep into the layers of the affected bowel tissue, leading to a range of symptoms including abdominal pain, severe diarrhea, fatigue, weight loss, and malnutrition. In the 8MM, diagnosed incident cases of CD are expected to increase from 118,885 cases in 2022 to 122,175 cases by 2032, reflecting an AGR of 0.28%. The U.S. is projected to have the highest number of diagnosed incident cases of CD in 2032, with 68,815 cases, while France is projected to report the fewest at 4,560 cases. Additionally, diagnosed prevalent cases of CD are anticipated to rise from 1,626,752 in 2022 to 1,695,580 in 2032, with an AGR of 0.42%. The U.S. is again

projected to lead in prevalence in 2032, with 755,802 cases, whereas Japan is projected to have the fewest diagnosed prevalent cases of CD at 44,732. These increases in diagnosed cases are attributed to changes in population dynamics across these markets. The global market for CD treatments was valued at $13.9 billion in 2022 and is projected to grow to approximately $25.5 billion in 2032 at a CAGR of approximately 6%. This market growth is fueled by the rising prevalence of the disease, improved diagnostic techniques, and ongoing advancements in research and development activities for new drug therapies.

FSCD, a severe form of CD, is characterized by the formation of fibrotic tissue, or strictures, in the bowel, which can result in obstruction and significant complications. Approximately half of CD patients will develop stricture formation within the first 10 years of diagnosis. Currently, treatment options for FSCD are limited, with no FDA-approved or effective pharmacologic treatments. Existing treatment approaches are primarily invasive, including balloon dilation, strictureplasty, and, in more severe cases, bowel resection. These procedures, while necessary, pose significant risks and can greatly impact the quality of life.

Given the lack of effective treatment options, we believe PALI-2108 has the potential to provide a much needed first-in-class therapy for these patients. PDE4 inhibitors are clinically and commercially proven dual-acting anti-inflammatory and anti-fibrotic agents, offering a unique approach to addressing both the inflammatory and fibrotic components of CD. With its innovative mechanism of action, PALI-2108 has the potential to transform the lives of individuals suffering from FSCD by providing a less invasive and more effective treatment alternative.

Unmet Needs in IBD

Despite the availability of various treatments, there are significant unmet needs in managing IBD. These challenges impact patient outcomes and overall disease management. We believe improvements to key existing therapies in IBD are necessary.

- Inadequate Primary Response to Medical Treatment - *Many patients experience low rates of clinical response to initial medical treatments.*
- Secondary Loss of Clinical Response or Drug Intolerance – *A portion of patients initially respond well to treatment but later experience a loss of clinical response or develop intolerance to currently available drugs.*
- Patient Selection - *Identifying patients likely to respond to specific drugs is critical.*
- Safety Concerns and Long-Term Medication Use - *Existing drugs may have side effects and safety concerns, including black box warnings, associated with prolonged use.*
- Limited Options for Refractory or Severe Disease – *A portion of patients face refractory or severe disease that does not respond adequately to available treatments.*
- Enhancing Treatment Adherence **--***Frequent or inconvenient dosing regimens, including infusions and injections, can hinder patient adherence.*

Based on our clinical research and development, we believe that PALI-2108 has the potential to address many of these areas of needed improvement.

Strategic Agreements and Collaborations

Research Collaboration and License Agreement with Giiant

On September 1, 2023, we entered into a research collaboration and license agreement, as amended, with Giiant Pharma, Inc. ("Giiant") (the "Giiant License Agreement"). Pursuant to the terms of the Giiant License Agreement, we obtained the rights to develop, manufacture, and commercialize all compounds from Giiant, existing now and in the future, and any product containing or delivering any licensed compound, in any formulation or dosage for all human and non-human therapeutic uses for any and all indications worldwide, including those technologies that are the basis of PALI-2108. In accordance with the terms of the Giiant License Agreement, preclinical development of PALI-2108 was jointly undertaken by us and representatives of Giiant. Pursuant to the Giiant License Agreement, we paid, or reimbursed or advanced to Giiant, a portion of the joint development costs. Additionally, per the terms of the Giiant License Agreement, we will pay (i) certain milestone payments (in cash or our common stock at our sole election) (the "Giiant Milestone Payments") and (ii) royalty payments upon sales or sublicenses to third parties, with

such Giiant Milestone Payments and royalty payments (the "Giiant License Payments") subject to a payment cap. With the approval to commence the Phase 1 clinical trial of PALI-2108, which we received from Health Canada on October 9, 2024, we have assumed all development, manufacturing, regulatory and commercialization activities and costs of PALI-2108.

Co-Development and Distribution Agreement with Newsoara

Prior to the completion of the Seneca Merger, LBS entered into a co-development and distribution agreement with Newsoara, a joint venture established with Biolead Medical Technology Limited, as amended, (the "Newsoara Co-Development Agreement"). Pursuant to the Newsoara Co-Development Agreement (and subsequent assignment agreement), LBS granted or licensed Newsoara an exclusive right under certain patents to develop, use, sell, offer to sell, import, and otherwise commercialize licensed products (the "Newsoara Licensed Products") for any and all indications in the People's Republic of China, including the regions of Hong Kong and Macao, but excluding Taiwan (the "Territory"). The Newsoara Licensed Products only include the drug asset LB1148, which we ceased developing in August of 2023. The right includes the right to grant sublicenses to third parties, subject to LBS' written consent, provided that both parties agreed that Newsoara would be permitted to use a certain partner for development purposes. The Newsoara Co-Development Agreement obligates Newsoara to initially use LBS as the exclusive supplier for all of Newsoara's requirements for Newsoara Licensed Products in the Territory. During the term of the Newsoara Co-Development Agreement, Newsoara may request to manufacture the Newsoara Licensed Products in the Territory, subject to satisfying certain conditions to LBS' reasonable satisfaction. LBS is obligated to approve Newsoara manufacturing rights without undue refusal or delay.

License Agreements with the Regents of the University of California

Prior to the Seneca Merger, LBS entered into three license agreements, as amended, with the Regents of the University of California ("Regents") for exclusive commercial rights to certain patents, technology and know-how related to LB1148. Concurrent with our decision to terminate the development of LB1148, on October 20, 2023 we terminated two of our license agreements with Regents. As of December 31, 2025, the only license agreement remaining with Regents is that entered into with LBS in August 2015, as amended in December 2019 and September 2022 (the "2015 UC License"). The 2015 UC License was retained for the sole purpose of maintaining the Newsoara Co-Development Agreement under which we may receive future milestone or royalty payments through the term of the license.

Commercial

Should any of our product candidates be approved for commercialization, we intend to develop a plan to commercialize them in the U.S. and other key markets, through internal infrastructure and/or external partnerships in a manner that will enable us to realize the full commercial value of our programs. Given our stage of development, we have not yet established a commercial organization or distribution capabilities.

Manufacturing and Supply

We do not currently own or operate facilities for product manufacturing, testing, storage, and distribution. We rely on third parties for our clinical supply of the API used in PALI-2108 and the PALI-2108 drug product and to supply the Newsoara Licensed Products to Newsoara.

As we progress through the research and clinical trials of our lead clinical product candidate, our strategy for manufacturing and supply chain management is designed to ensure the highest quality, compliance, and efficiency in producing our product candidates.

To support the clinical manufacture of the product candidates we are developing, we engage a network of third-party Contract Development and Manufacturing Organizations ("CDMOs") and Contract Manufacturing Organizations ("CMOs"). These partnerships are strategically chosen based on a rigorous review of criteria including technological capabilities, regulatory compliance, quality assurance systems, and production capacity.

Our selection process for CDMOs and CMOs involves an in-depth evaluation of potential partners to ensure alignment with our quality standards, production needs, and timeline requirements. These organizations are responsible for various stages of drug development and manufacturing, including but not limited to:

- *API Production:* High-quality synthesis of active ingredients under stringent regulatory standards.

- *Formulation Development:* Design and development of stable and effective drug formulations suitable for clinical trials.
- *Clinical Trial Material Manufacturing:* Production of investigational medicinal products in compliance with current Good Manufacturing Practice ("cGMP") regulations for use in clinical trials.
- *Packaging and Labeling:* Secure and compliant packaging and labeling solutions for clinical trial materials, ensuring patient safety and regulatory adherence.
- *Quality Control and Assurance:* Comprehensive testing and validation processes to ensure the safety, efficacy, and quality of the clinical supplies.

PALI-2108

We currently have agreements in place with third parties to provide the necessary clinical supply of our API. These agreements are generally non-specific master services agreements that allow an entity to begin the process of future manufacturing or toxicology services, respectively.

LB1148

Pursuant to our Newsoara Co-Development Agreement, we are Newsoara's exclusive supplier of the Newsoara Licensed Products. We currently have an agreement with a third-party to supply us with the Newsoara Licensed Products as required under the Newsoara Co-Development Agreement. The agreement is a non-specific master services agreement that allows us to alter the scope of services as needed.

Competition

As a clinical biopharmaceutical company, we face competition from a wide array of companies in the pharmaceutical and biotechnology industries. We also compete with the intellectual property, technology, and product development efforts of academic, governmental, and private research institutions.

We operate in a competitive landscape within the biopharmaceutical industry. Our focus on PDE4 inhibitor prodrugs that are locally acting and the use of precision medicine for IBD presents both opportunities and challenges.

While PDE4 inhibitors that are systemically available have been demonstrated to have significant efficacy, most have demonstrated dose-limiting toxicity. Also, precision medicine has been successfully applied in oncology and its adoption in IBD remains an unmet need. Our competitors include established biopharmaceutical companies, emerging biopharmaceutical companies, and generic manufacturers.

Large pharmaceutical companies with extensive resources and established pipelines compete in the IBD space. Their existing products and research efforts pose a significant challenge to our ability to compete. These competitors have a track record of developing and commercializing therapies for IBD, which may impact our market share.

Emerging public and private biotech companies are also working to develop novel therapeutics for the treatment of IBD. However, we are not aware of other PDE4 inhibitors for FSCD in development and only one other PDE4 inhibitor for UC in development in China. Emerging biotech companies have similar agility and focus as us, allowing them to explore novel approaches. We compete with these emerging companies for funding, talent, and market attention.

Generic and biosimilar manufacturers are developing generic versions of existing IBD drugs and biosimilars are a threat to the market. As patents expire, competition intensifies. We believe that by using a precision medicine approach, we can differentiate our PDE4 inhibitor from generic alternatives, although we are not currently aware of any PDE4 inhibitors approved for IBD that will become generic.

The key competitive factors affecting the success of any products that we develop, if approved, are likely to be their efficacy, safety, convenience, price, and the availability of reimbursement from government and other third-party payors. Our commercial opportunity for any of our product candidates could be reduced or eliminated if our competitors develop and commercialize products that are more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any products that we may develop. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, and they may commercialize products more quickly than we do.

If approved for the treatment of patients with moderate-to-severe IBD, our portfolio of products would compete with TNF antibodies including Humira (AbbVie) and its biosimilars, Remicade (Johnson & Johnson) and its biosimilars, and Simponi (Johnson & Johnson); IL-12/23 antibodies including Stelara (Johnson & Johnson) and its biosimilars; IL-23 antibodies including Skyrizi (AbbVie), Tremfya (Johnson & Johnson) and Omvoh (Eli Lilly); α4ß7 antibody Entyvio (Takeda); JAK inhibitors including Xeljanz (Pfizer) and Rinvoq (AbbVie); and S1P1 receptor modulating therapies including Zeposia (Bristol Myers Squibb) and Pelsipity (Pfizer).

We are aware of several companies with product candidates in development for the treatment of patients with IBD including, but not limited to, Merck's MK-7240, Johnson & Johnson's JNJ-2113, Genentech's RO7790121, Teva's TEV-48574, Morphic Therapeutic's MORF-057, Ventyx's VTX002, and several being developed by Spyre Therapeutics including SPY001, SPY002, SPY003, SPY120, SPY130 and SPY230.

These technologies, along with other modalities, such as small molecules and biologics, may be used to develop therapeutic candidates that would compete against our current, and potentially future, product candidates.

Intellectual Property

Patents

We have exclusively licensed a worldwide patent portfolio from Giiant consisting of pending patent applications related to the assets licensed, including PALI-2108. In the U.S., we have exclusive rights to one pending patent application. Internationally, we have exclusive rights to six pending patent applications. In July of 2025, we announced that the China National Intellectual Property Administration issued a Notice of Allowance for our patent covering PALI-2108 in China. In December of 2025, we announced that the Japan Patent Office granted our patent covering PALI-2108 in Japan.

The pending patents relate to (i) methods of making pharmaceutical composition, (ii) the pharmaceutical compositions, and (iii) the methods of using the pharmaceutical compositions, including PALI-2108 and the other assets licensed from Giiant, to treat UC, Crohn's disease and other disorders.

We have also filed a provisional patent application relating to methods of medical use and personalized treatment with PALI-2108, which is currently pending. This provisional application covers methods for selecting patients suffering from inflammatory diseases who are more likely to respond to treatment with an oral PDE4 inhibitor, including selection based on disease characteristics and biomarkers associated with treatment response.

In addition, we have filed a provisional patent application covering pharmaceutical compositions of PALI-2108 designed for delayed, targeted, and sustained release in the gastrointestinal tract. These compositions enable localized drug delivery to the terminal ileum and colon and support once-daily oral dosing through controlled release and extended pharmacokinetics.

In addition to our pending patents related to PALI-2108, we also maintain a patent in China related to LB1148 with the Regents of the University of California to support our co-development agreement with Newsoara. The expected expiration date of this patent is 2031, excluding any adjustments or extensions of patent term that may be available.

U.S. Government Regulation and Product Approval

In the U.S., the FDA regulates pharmaceutical products under the Federal Food, Drug, and Cosmetic Act ("FDCA"), the Public Health Services Authority ("PHSA"), and regulations and guidance documents implementing these laws. The FDCA, PHSA and their corresponding regulations govern, among other things, the development, testing, manufacturing, safety, effectiveness, purity, potency, labeling, packaging, storage, quality control, record keeping, distribution, post-approval monitoring and reporting, sampling, advertising and other promotional practices and export and import involving pharmaceutical products. Consent from the FDA is required before conducting human clinical testing of drug products. We, along with our vendors, collaboration partners, contract research organizations ("CROs") and CMOs, will be required to navigate the various preclinical, clinical, manufacturing and commercial approval requirements of the FDA and other governing regulatory agencies of the countries in which we wish to conduct studies or seek approval of our product candidates. The process of obtaining regulatory approvals of drug products and ensuring subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations requires the expenditure of substantial time and financial resources.

U.S. Small Molecule New Drug Product Development Process

Any new drug product must be approved by the FDA before it may be legally marketed in the U.S. FDA approval is also required before marketing an approved drug product for a new indication or condition of use. The process required by the FDA before a new drug product candidate may be marketed in the U.S. generally involves the following:

- Completion of preclinical laboratory tests and in vivo studies in accordance with the FDA's Good Laboratory Practice ("GLP") regulations and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- Submission to the FDA of an IND application, which allows human clinical trials to begin unless FDA objects (issues a "clinical hold") within 30 calendar days;
- Approval by an independent institutional review board ("IRB"), reviewing each proposed clinical trial and clinical site before each clinical trial may be initiated;
- Performance of adequate and well-controlled human clinical trials in accordance with the protocol contained in the approved IND and in accordance with the FDA's Good Clinical Practice ("GCP") regulations, and any additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the proposed product candidate for its intended use;
- Preparation and submission to the FDA of an new drug application ("NDA") for marketing approval that includes substantial evidence of safety and efficacy from results of preclinical testing and clinical trials;
- Review of the product by an FDA advisory committee, if applicable;
- Satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the product candidate is produced to assess compliance with cGMP regulations and to assure that the facilities, methods and controls are adequate to preserve the product candidate's identity, safety, strength, quality, potency and purity;
- Potential FDA audit of the preclinical and clinical trial sites that generated the data supporting the NDA; and,
- Payment of user fees and FDA review and approval of the NDA.

The testing and approval process of product candidates requires substantial time, effort, and financial resources. Satisfaction of the FDA's pre-market approval requirements typically takes many years, and the actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease. Before testing any product candidate in humans, the product candidate must undergo preclinical testing. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as in vivo animal studies to assess the potential safety and activity of the product candidate and to establish a rationale for therapeutic use. The conduct of the preclinical tests must comply with federal regulations and requirements including GLPs regulations.

Concurrent with clinical trials, companies usually must complete some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the drug in commercial quantities in accordance with cGMP regulations. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

A clinical trial sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes active 30 calendar days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to a proposed clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks, and places the clinical trial on a clinical hold. A clinical hold is an order issued by the FDA to the sponsor to delay a

proposed clinical investigation or to suspend an ongoing investigation. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA also may impose partial or full clinical holds on a product candidate at any time before or during clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, trials may not begin or recommence without FDA authorization and then only under terms authorized by the FDA. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, that issues arise that partially or fully suspend or terminate such studies.

Human Clinical Trials in the U.S. Under an IND

Clinical trials involve the administration of the investigational product to healthy volunteers or patients under the supervision of qualified investigators, which are generally physicians not employed by, or under, the control of the trial sponsor. Clinical trials must be conducted under written study protocols detailing, among other things, the objectives of the trial, subject selection and exclusion, the trial procedures, the parameters to be used in monitoring safety, the criteria to be evaluated, and a statistical analysis plan. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND.

Further, clinical trials must be conducted in accordance with federal regulations and GCP requirements, which include the requirements that all research subjects provide their informed consent in writing for their participation in any clinical trial, as well as review and approval by an IRB at each study site participating in the clinical trial or a central IRB. An IRB is charged with protecting the welfare and rights of trial participants and considers items such as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject, or their legal representative, reviews and approves the study protocol, and must monitor the clinical trial until completed.

Human clinical trials typically are conducted in three sequential phases that may overlap or be combined:

- Phase 1. The product candidate initially is introduced into a small number of healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early understanding of its value in treating patients. In the case of some product candidates for severe or life-threatening diseases, especially when the product candidate may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients with the indicated disease.
- Phase 2. The product candidate is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product candidate for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more extensive Phase 3 clinical trials.
- Phase 3. Phase 3 clinical trials are commonly referred to as “pivotal” or “registrational” studies, which typically denotes a study that presents data the FDA or other relevant regulatory agency will use to determine whether to approve a product. In Phase 3 studies, the product candidate is administered to an expanded patient population, generally at multiple geographically dispersed clinical trial sites in adequate and well-controlled clinical trials to generate sufficient data to statistically demonstrate the efficacy and safety of the product for approval. These clinical trials are intended to establish the overall risk/benefit ratio of the product candidate and provide an adequate basis for product labeling. Generally, two adequate and well-controlled Phase 3 clinical trials are required by the FDA for approval of an NDA, although the FDA will sometimes accept one Phase 3 clinical trial if there is other supporting evidence of efficacy and safety.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be required by FDA, or may be voluntarily conducted after initial approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA.

IND safety reports must be promptly submitted to the FDA and the investigators for: serious and unexpected adverse events; any findings from other studies, in vivo laboratory tests or in vitro testing that suggest a significant risk for human subjects; or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. Specifically, the sponsor must submit an IND safety report within seven calendar days of any unexpected fatal or life-threatening suspected adverse reaction and 15 calendar days of any serious and unexpected adverse events as described above. Relevant additional information obtained by the sponsor that pertains to a previously submitted IND safety report must be submitted as a follow-up IND safety report. Such report should be submitted within 15 calendar days after the sponsor receives the additional information.

Information about certain clinical trials, including a description of the study and, in some cases, study results, must be submitted within specific timeframes to the National Institutes of Health for public dissemination on their clinicaltrials.gov website. Manufacturers or distributors of investigational products for the diagnosis, monitoring, or treatment of one or more serious or life-threatening diseases or conditions where no other comparable or satisfactory therapeutic options exist must also have a publicly available policy on evaluating and responding to requests for expanded access, sometimes called "compassionate use" requests.

Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor that regularly reviews accumulated data and advises the study sponsor regarding the continuing safety of the trial. This group, known as a Data and Safety Monitoring Board or Data and Safety Monitoring Committee, may also review interim data to assess the continuing validity and scientific merit of the clinical trial. This group receives special access to unblinded data during the clinical trial and may advise the sponsor to halt the clinical trial if it determines there is an unacceptable safety risk for subjects or on other grounds, such as no demonstration of efficacy.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements or if the trial poses unexpected serious harm to subjects. The FDA or an IRB may also impose conditions on the conduct of a clinical trial. Clinical trial sponsors may also choose to discontinue clinical trials as a result of risks to subjects, a lack of favorable results, or changing business priorities.

A sponsor may choose, but is not required, to conduct a foreign clinical study under an IND. When a foreign clinical study is conducted under an IND, all IND requirements must be met unless waived. When the foreign clinical study is not conducted under an IND, the sponsor must ensure that the study complies with certain FDA regulatory requirements in order to use the study as support for an IND or application for marketing approval. Specifically, FDA has promulgated regulations governing the acceptance of foreign clinical trials not conducted under an IND, establishing that such studies will be accepted as support for an IND or application for marketing approval if the study was conducted in accordance with GCP requirements, including review and approval by an ethics committee, and use of proper procedures for obtaining informed consent from subjects, and the FDA is able to validate the data from the study through an on-site inspection if FDA deems such inspection necessary. The GCP requirements encompass both ethical and data integrity standards for clinical studies. The FDA's regulations are intended to help ensure the protection of human subjects enrolled in non-IND foreign clinical trials, as well as the quality and integrity of the resulting data. They further help ensure that non-IND foreign studies are conducted in a manner comparable to that required for IND studies. If a marketing application is based solely on foreign clinical data, the FDA requires that the foreign data be applicable to the U.S. population and U.S. medical practice; the studies must have been performed by clinical investigators of recognized competence; and the FDA must be able to validate the data through an on-site inspection or other appropriate means, if the FDA deems such an inspection to be necessary.

Compliance with cGMP Regulations

Manufacturers of pharmaceutical products must comply with applicable cGMP regulations, including quality control and quality assurance and maintenance of records and documentation. Manufacturers and others involved in the manufacture and distribution of such products also must register their establishments with the FDA and certain state agencies. Both domestic and foreign manufacturing establishments must register and provide additional information to the FDA upon their initial participation in the manufacturing process. Establishments may be subject to periodic, unannounced inspections by government authorities to ensure compliance with cGMP regulations and other laws. Discovery of problems may result in a government entity placing restrictions on a product, manufacturer or holder

of an approved NDA, and may extend to requiring withdrawal of the product from the market. The FDA will not approve an NDA unless it determines that the manufacturing processes and facilities are in compliance with cGMP regulations and adequate to assure consistent production of the product within required specification.

Concurrently with clinical trials, companies usually complete additional preclinical studies and must also develop additional information about the physical characteristics of the product candidate as well as finalize a process for manufacturing the product candidate in commercial quantities in accordance with cGMP regulations. To help reduce the risk of the introduction of adventitious agents or of causing other adverse events with the use of small molecule products, the PHSA emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other requirements, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted, to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

In relation to the clinical trials that may be conducted in other countries with a view to obtaining a marketing authorization, there are comparable cGMP regulations and other regulatory rules that are implemented nationally.

U.S. FDA Review and Approval Process

Assuming successful completion of the required clinical and preclinical testing, the results of the preclinical tests and clinical trials together with detailed information relating to the product's CMC, including negative or ambiguous results as well as positive findings, and proposed labeling, among other things, are submitted to the FDA for NDA approval to market the product for one or more indications. Data may come from company-sponsored clinical trials intended to test the safety and effectiveness of a product, or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and effectiveness of the investigational drug product to the satisfaction of the FDA.

Under the Prescription Drug User Fee Act ("PDUFA"), as amended, each NDA must be accompanied by a significant user fee. The FDA adjusts the PDUFA user fees on an annual basis. The PDUFA also imposes an annual program fee for approved therapeutic products. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs for product candidates designated as orphan drugs, unless the product candidate also includes a non-orphan indication.

In addition, under the Pediatric Research Equity Act ("PREA"), an NDA for a new active ingredient, indication, dosage form, dosage regimen, or route of administration, must contain data that are adequate to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe. Also, applications for product candidates intended for the treatment of adult cancer directed at molecular targets that the FDA determines to be substantially relevant to the growth or progression of pediatric cancer, in place of the PREA investigations, sponsors must submit, with the application, reports from molecularly targeted pediatric cancer investigations designed to yield clinically meaningful pediatric study data, using appropriate formulations, to inform potential pediatric labeling. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Orphan products are also exempt from the PREA requirements.

The FDA reviews an NDA within 60 days of submission to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any NDA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In that event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth, substantive review of the NDA.

The FDA reviews the NDA to determine, among other things, whether the proposed product candidate is safe and effective for its intended use, has an acceptable purity profile and whether the product candidate is being manufactured in accordance with cGMP regulations to assure and preserve the product candidate's identity, safety, strength, quality, potency and purity. The FDA may refer applications for novel therapeutic products or therapeutic products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application

should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the product approval process, the FDA also will determine whether a risk evaluation and mitigation strategy, ("REMS") is necessary to assure the safe use of the product candidate. REMS use risk minimization strategies beyond the professional labeling to ensure that the benefits of the product outweigh the potential risks. To determine whether a REMS is needed, the FDA will consider the size of the population likely to use the product, seriousness of the disease, expected benefit of the product, expected duration of treatment, seriousness of known or potential adverse events, and whether the product is a new molecular entity. A REMS could include medication guides, physician communication plans and elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS; the FDA will not approve the NDA without a REMS, if required.

Before approving an NDA, the FDA will inspect the facilities at which the product candidate is manufactured. The FDA will not approve the product candidate if it determines that the manufacturing processes and facilities are not in compliance with cGMP regulations or otherwise are not adequate to assure consistent production of the product candidate within required specifications. Additionally, before approving an NDA, the FDA typically will inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND trial requirements and GCP requirements.

On the basis of the NDA and accompanying information, including the results of the inspection of the manufacturing facilities, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter.

If a product candidate receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing or dispensing in the form of a REMS, or otherwise limit the scope of any approval. The FDA may also require post-marketing clinical trials, sometimes referred to as Phase 4 clinical trials, designed to further assess a product's safety, and testing and surveillance programs to monitor the safety of approved products that have been commercialized.

Every five years, the FDA agrees to specified performance goals in the review of NDAs under the PDUFA. One such current goal is to review standard NDAs in ten months after the FDA accepts the NDA for filing, and priority NDAs in six months, whereupon a review decision is to be made. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs and its review goals are subject to change from time to time. The review process and the PDUFA goal date may be extended by three months if the FDA requests or the NDA sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

U.S. Expedited Development and Review Programs

The FDA has various programs, including fast track designation, accelerated approval, priority review, and breakthrough therapy designation, which are intended to expedite and facilitate the process for the development and the FDA review of drugs that are intended for the treatment of serious or life-threatening diseases or conditions and demonstrate the potential to address unmet medical needs, and to provide patients with access to the drugs more quickly than standard FDA review timelines typically permit.

The Fast Track program that is intended to expedite or facilitate the process for reviewing new drugs and biologics that meet certain criteria. Specifically, new drugs and biologics are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and preclinical or clinical data demonstrate the potential to address unmet medical needs for the condition. The FDA will determine that a product will fill an unmet medical need if it will provide a therapy where none exists or provide a therapy that may be potentially superior to existing therapy based on efficacy, or safety or other factors. Fast track designation provides increased opportunities for sponsor interactions with the FDA during preclinical and clinical development. The FDA may also review sections of the NDA for a fast track product on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept those sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission

of the first section of the NDA. If the FDA accepts a portion of an application, this does not necessarily mean that review will commence or proceed before the complete application is submitted. Actual commencement and scheduling of review depends on many factors, including staffing, workload, competing priorities, timeline for completing the application, and the perceived efficiency of commencing review before receipt of the complete submission. Fast Track designation applies to both the product and the specific indication for which it is being studied. The sponsor can request the FDA to designate the product for Fast Track status any time before receiving NDA approval, but ideally no later than the pre-NDA meeting.

The FDA may give a priority review designation to drugs that, if approved, would provide a significant improvement in safety or effectiveness in the treatment, diagnosis or prevention of a serious disease or condition. A priority review means that the goal for the FDA to review an application is six months, rather than the standard review of 10 months under current PDUFA guidelines. These six-and 10-month review periods are measured from the "filing" date rather than the receipt date for NDAs for new molecular entities, which typically adds approximately two months to the timeline for review and decision from the date of submission. Products that are eligible for Fast Track designation may also be eligible for priority review.

A product may also be eligible for accelerated approval if it is intended to treat a serious or life-threatening condition and generally provide a meaningful advantage over available therapies. Such products may be approved on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. If the FDA concludes that a drug shown to be effective can be safely used only if distribution or use is restricted, it may require such post-marketing restrictions as it deems necessary to assure safe use of the product. Additionally, under the Food and Drug Omnibus Reform Act of 2022 ("FDORA"), the FDA is now permitted to require, as appropriate, that such trials be underway prior to approval or within a specific time period after the date of approval for a product granted accelerated approval. Under FDORA, the FDA has increased authority for expedited procedures to withdraw approval of a drug or an indication approved if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product. In addition, the FDA currently requires pre-approval of promotional materials as a condition for accelerated approval, which could adversely impact the timing of the commercial launch of the product. Drugs granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

Sponsors can also request designation of a drug candidate as a "breakthrough therapy." A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. A drug that receives breakthrough therapy designation is eligible for certain FDA actions as appropriate, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy. The designation includes all the benefits of a Fast Track designation in addition to intensive guidance on an efficient drug development program beginning as early as Phase 1, and FDA organizational commitment to expedited development, including involvement of senior managers and experienced review staff in a cross-disciplinary review, where appropriate. The breakthrough therapy designation is a distinct status from both accelerated approval and priority review, which can also be granted to the same drug if relevant criteria are met.

FDA recently announced the Commissioner's National Priority Voucher ("CNPV") pilot program, which is a new program designed to accelerate the review of products with the potential to address one or more of the following key national priorities: addressing a U.S. public health crisis, delivering more innovative cures for the American people, addressing a large unmet medical need, promoting domestic drug development and manufacturing to advance the health interests of Americans and strengthen U.S. supply chain resiliency, and increasing the accessibility and affordability of drugs and biologics. Voucher recipients receive enhanced communications with review staff throughout the development process, and review decisions are targeted for completion within 1-2 months following submission of an application. Critics of the CNPV program have raised concerns that the program may run afoul of legal, ethical and scientific standards long used to vet the safety and effectiveness of new medicines, causing some companies to decide not to seek participation in the program.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. Furthermore, fast track designation, accelerated approval, priority review, and breakthrough therapy designation do not change the standards for approval but may expedite the development or review process. We may explore some of these opportunities for our product candidates as appropriate.

U.S. Post-Approval Requirements

After approval, there are continuing annual program user fee requirements for approved products, excluding, under certain circumstances, orphan products.

Rigorous and extensive FDA regulation of pharmaceutical products continues after approval, particularly with respect to cGMP regulations. Manufacturers are required to comply with applicable cGMP regulations, including quality control and quality assurance and maintenance of records and documentation. To help reduce the increased risk of the introduction of adventitious agents, the PHSA emphasizes the importance of manufacturing controls for products whose attributes cannot be precisely defined. The PHSA also provides authority to the FDA to immediately suspend licenses in situations where there exists a danger to public health, to prepare or procure products in the event of shortages and critical public health needs, and to authorize the creation and enforcement of regulations to prevent the introduction or spread of communicable diseases in the U.S. and between states.

Other post-approval requirements applicable to pharmaceutical products include reporting of deviations from cGMP regulations that may affect the identity, potency, purity and overall safety of a distributed product, record-keeping requirements, reporting of adverse effects, reporting updated safety and efficacy information, and complying with electronic record and signature requirements. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, and potency of pharmacological products.

In addition, manufacturers and other entities involved in the manufacture and distribution of approved pharmaceuticals are required to register their establishments with the FDA and certain state agencies, list their products, and are subject to periodic announced and unannounced inspections by the FDA and these state agencies for compliance with cGMP regulations and other requirements, which impose certain procedural and documentation requirements upon us and third-party manufacturers. Manufacturers must continue to expend time, money, and effort in the areas of production and quality-control to maintain compliance with cGMP regulations. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered. In addition, changes to the manufacturing process or facility generally require prior FDA approval or notification before being implemented, and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

Moreover, the Drug Quality and Security Act imposes obligations on manufacturers of pharmaceutical products related to product tracking and tracing.

Adverse event reporting and submission of periodic reports, including annual reports and deviation reports, are required following FDA approval of an NDA. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in significant regulatory actions. Such actions may include refusal to approve pending applications, license suspension or revocation, imposition of a partial or full clinical hold or termination of clinical trials, warning letters, untitled letters, modification of promotional materials or labeling, provision of corrective information, imposition of post-market requirements including the need for additional testing, imposition of distribution or other restrictions under a REMS, product recalls, product seizures or detentions, refusal to allow imports or exports, total or partial suspension of production or distribution, FDA debarment, injunctions, fines, consent decrees, corporate integrity agreements, suspension and debarment from government contracts, and refusal of orders under existing government contracts, exclusion from participation in federal and state healthcare programs, restitution, disgorgement, or civil or criminal penalties, including fines and imprisonment, and result in adverse publicity, among other adverse consequences.

A sponsor also must comply with the FDA's advertising and promotion requirements, such as the prohibition on promoting products for uses or in patient populations that are inconsistent with the product's approved labeling (known as "off-label use"). The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. Violations relating to the promotion of off-label uses may lead to investigations alleging

violations of federal and state healthcare fraud and abuse and other laws, as well as state consumer protection laws. Companies, however, may generally share truthful and non-misleading information that is otherwise consistent with a product's FDA approved labeling. Discovery of previously unknown problems or the failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions.

Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant or manufacturer to administrative or judicial civil or criminal actions and adverse publicity. These actions could include refusal to approve pending applications or supplemental applications, withdrawal of an approval, clinical hold, suspension or termination of a clinical trial by an IRB, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines or other monetary penalties, refusals of government contracts, mandated corrective advertising or communications with healthcare providers, debarment, restitution, disgorgement of profits or other civil or criminal penalties. Physicians may prescribe, in their independent professional medical judgment, legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate physicians in their practice of medicine, including their choices of treatments for their patients. The FDA does, however, restrict drug manufacturer's communications on the subject of off-label use of their products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined companies from engaging in off-label promotion. The FDA and other regulatory agencies have also required that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. However, companies may share certain truthful and non-misleading information that is otherwise consistent with a product's FDA-approved labeling.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, as amended ("PDMA"), which regulates the distribution of drugs and drug samples at the federal level and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

Broadly equivalent requirements and controls typically apply in other countries to the submission of marketing authorization applications and, post-approval, to the holding of such marketing authorizations.

The Hatch-Waxman Amendments and Generic Competition

Orange Book Listing

Once a drug product is approved under an NDA, the product is listed in the FDA's publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the Orange Book. An NDA-approved drug product will be designated in the Orange Book as a Reference Listed Drug ("RLD"). Sponsors of approved NDAs are required to list with the FDA patents whose claims cover the product's active ingredient, formulation, or an approved method of using the drug.

Patent Term Extensions

Depending upon the timing, duration and specifics of FDA approval of the use of our therapeutic candidates, some of our U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Amendments to the FDCA ("Hatch-Waxman"). Hatch-Waxman permits a patent restoration term of up to five years as compensation for patent term lost during drug product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product or therapeutic candidate's approval date. The patent term restoration period is generally one half of the time between the effective date of an IND and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved product or therapeutic candidate is eligible for the extension and the application for extension must be made prior to expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we intend to apply for restorations of patent term for some of our currently owned or licensed patents to add

patent life beyond their current expiration date, depending on the expected length of clinical trials and other factors involved in the submission of the relevant NDA(s).

ANDA Approval Process for Generic Drugs

Hatch-Waxman also established an abbreviated FDA approval process for generic drugs that are shown to be pharmaceutically equivalent and bioequivalent to drugs previously approved by the FDA through the NDA process. Approval to market and distribute these drugs is obtained by filing an abbreviated new drug application ("ANDA"), with the FDA. An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown to be bioequivalent to the listed drug. An ANDA is a comprehensive submission that contains, among other things, data and information pertaining to the API, drug product formulation, specifications and stability of the generic drug, as well as analytical methods, manufacturing process validation data and quality control procedures. ANDAs are termed abbreviated because they generally do not include preclinical and clinical data to demonstrate safety and effectiveness. Instead, a generic applicant must demonstrate that its product is bioequivalent to the innovator drug. In some cases involving drugs with no or limited systemic absorption, an ANDA must include clinical endpoint (efficacy) studies in order to demonstrate bioequivalence. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug and can often be substituted by pharmacists under prescriptions written for the original listed drug.

Section 505(b)(2) NDA Approval Process

As an alternative path to FDA approval for modifications to formulations or uses of products previously approved by the FDA under a "full" NDA, an applicant may submit an NDA under Section 505(b)(2) of the FDCA. Section 505(b)(2) was enacted as part of the Hatch-Waxman Amendments and enables the applicant to rely, in part, on the FDA's previous approval of a similar product, and/or published literature, in support of the safety and/or efficacy of its drug product. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference. If the Section 505(b)(2) applicant can establish that reliance on FDA's previous findings of safety and effectiveness is scientifically appropriate, it may eliminate the need to conduct certain preclinical studies or clinical trials of the new product. The FDA may also require companies to perform additional studies or measurements, including clinical trials, to support the change from the approved reference drug. The FDA may then approve the new product candidate for all, or some, of the label indications for which the reference drug has been approved or for any new indication sought by the Section 505(b)(2) applicant.

ANDA and 505(b)(2) products may be significantly less costly to bring to market than the reference listed drug, and companies that produce generic products are generally able to offer them at lower prices. Moreover, generic versions of RLDs are often automatically substituted for the RLD by pharmacies when dispensing a prescription written for the RLD. Thus, following the introduction of a generic drug, a significant percentage of the sales of any branded product or reference listed drug is typically lost to the generic product.

ANDA and 505(b)(2) NDA Patent Certification Requirements

Any applicant who files an ANDA seeking approval of a generic equivalent version of a drug listed in the Orange Book or a Section 505(b)(2) NDA referencing a drug listed in the Orange Book must certify to the FDA, as applicable, that (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is, in the applicant's opinion, invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. This last certification is known as a paragraph IV certification. If an ANDA or 505(b)(2) NDA is submitted to FDA with a Paragraph IV Certification, the applicant must also provide a "Paragraph IV Notification" to the holder of the NDA for the RLD and to the owner of the listed patent(s) being challenged by the applicant, providing a detailed written statement of the bases for the applicant's position that the relevant patent(s) is invalid or would not be infringed. If the patent owner brings a patent infringement lawsuit against the applicant within 45 days of the Paragraph IV Notification, FDA approval of the ANDA or 505(b)(2) NDA will be automatically stayed for 30 months, or until 7 ½ years after the RLD's NDA approval date if the ANDA or 505(b)(2) NDA was filed between 4 years and 5 years after the NDA approval. Any such stay will be terminated earlier if the court rules that the patent is invalid or would not be infringed. The applicant may, in certain circumstances, elect to submit a "section viii" statement with respect to a listed method of use patent, certifying that the proposed ANDA or 505(b)(2) product's labeling does not contain (or carves out) any language that would infringe a method of use patented listed in the Orange Book for the RLD.

The ANDA or 505(b)(2) application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the reference drug has expired as described in further detail below.

Regulatory Exclusivities

New Chemical Entity Exclusivity

The Hatch-Waxman Amendments provide a period of five years of non-patent marketing exclusivity for the first approved drug containing a new chemical entity ("NCE") as an active ingredient. An NCE is an active moiety that has not been approved by the FDA in any other NDA. A fixed combination drug product may receive NCE exclusivity if one of its active ingredients is an NCE, but not if all of its active ingredients have previously been approved. An "active moiety" is defined as the molecule or ion responsible for the drug substance's physiological or pharmacologic action. During the five-year exclusivity period, the FDA cannot accept for filing any ANDA or 505(b)(2) NDA seeking approval of a product that contains the same active moiety, except that the FDA may accept such an application for filing after four years if the application includes a paragraph IV certification to a listed patent.

New Clinical Trial (3-Year) Exclusivity

A drug, including one approved under Section 505(b)(2), may obtain a three-year period of exclusivity for a particular indication or condition of approval, or change to a marketed product, such as a new formulation for a previously approved product, if one or more new clinical trials (other than bioavailability studies) was essential to the approval of the application or supplemental application and was conducted/sponsored by the applicant. Should this occur, the FDA would be precluded from approving any ANDA or Section 505(b)(2) application for the protected modification until after that three-year exclusivity period has run. However, unlike NCE exclusivity, the FDA can accept an application and begin the review process during the three-year exclusivity period.

Orphan Drug Designation and Orphan Exclusivity Under the Orphan Drug Act

The FDA may grant orphan designation to a drug product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the U.S., or more than 200,000 individuals in the U.S. but for which there is no reasonable expectation that the cost of developing and making the product available in the U.S. for this type of disease or condition will be recovered from sales of the product.

Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years from the date of such approval, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity by means of greater effectiveness, greater safety, or providing a major contribution to patient care or in instances of drug supply issues. However, competitors may receive approval of either a different product for the same indication or the same product for a different indication but that could be used off-label in the orphan indication. Orphan drug exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval before we do for the same product, as defined by the FDA, for the same indication we are seeking approval, or if a product candidate is determined to be contained within the scope of the competitor's product for the same indication or disease. If one of our products is designated as an orphan drug and receives marketing approval for an indication broader than that for which it is designated, it may not be entitled to orphan drug exclusivity. Orphan drug status in the European Union has similar, but not identical, requirements and benefits.

Pediatric Exclusivity

Pediatric exclusivity is another type of non-patent marketing exclusivity available in the U.S. and, if granted, it provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity or listed patents. Under the Best Pharmaceuticals for Children Act certain therapeutic candidates may obtain an additional six months of exclusivity if the sponsor conducts pediatric research and submits new clinical information requested in writing by the FDA, referred to as a Written Request, relating to the use of the active moiety of the product or therapeutic candidate in children. The data need not support a label change for

pediatric use; rather, the additional protection is granted if the pediatric clinical trial is deemed to have fairly responded to the FDA's Written Request. Although the FDA may issue a Written Request for studies on either approved or unapproved indications, it may only do so where it determines that information relating to that use of a product or therapeutic candidate in a pediatric population, or part of the pediatric population, may produce health benefits in that population. The issuance of a Written Request does not require the sponsor to undertake the described trials. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application.

Other U.S. Healthcare Laws and Regulations

Our business activities, including but not limited to, research, sales, promotion, distribution, medical education, and other activities following product approval will be subject to regulation by numerous federal and state regulatory and law enforcement authorities in the U.S. in addition to the FDA, including potentially the Department of Justice, the Department of Health and Human Services ("HHS") and its various divisions, including the Office of Inspector General, the Centers for Medicare & Medicaid Services ("CMS") and the Health Resources and Services Administration, the Department of Veterans Affairs, the Department of Defense, and state and local governments. Healthcare providers and third-party payors play a primary role in the recommendation and use of pharmaceutical products that are granted marketing approval. Arrangements with third-party payors, existing or potential customers and referral sources, including healthcare providers, are subject to broadly applicable fraud and abuse laws and regulations, and these laws and regulations may constrain the business or financial arrangements and relationships through which manufacturers conduct clinical research, market, sell and distribute the products for which they obtain marketing approval. Such restrictions under applicable federal and state healthcare laws and regulations include the following:

- The federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or kind, in exchange for, or to induce, either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers, on the one hand, and prescribers, purchasers, formulary managers and other individuals and entities on the other. Although there are a number of statutory exemptions and regulatory safe harbors to the federal Anti-Kickback Statute protecting certain common business arrangements and activities from prosecution or regulatory sanctions, the exemptions and safe harbors are drawn narrowly, and practices that do not fit squarely within an exemption or safe harbor, or for which no exception or safe harbor is available, may be subject to scrutiny. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the "ACA") amended the intent requirement of the federal Anti-Kickback Statute such that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to commit a violation;
- The federal civil and criminal false claims, including the civil False Claims Act ("FCA"), and Civil Monetary Penalties Laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent, or making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government. Certain marketing practices, including off-label promotion, also may implicate the FCA. In addition, the ACA codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. Because of the threat of treble damages and mandatory penalties per false or fraudulent claim or statement under the FCA, healthcare and pharmaceutical companies often resolve allegations without admissions of liability for significant and material amounts;
- The federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, therapeutic products and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare and Medicaid Services ("CMS"), information related to payments and other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and

their immediate family members. Analogous state laws addressing these topics may also affect our arrangements;

- Health Insurance Portability and Accountability Act of 1996 ("HIPAA") prohibits knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, a healthcare benefit program, regardless of whether the payor is public or private, in connection with the delivery or payment for health care benefits, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense and knowingly and willfully falsifying, concealing, or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items, or services relating to healthcare matters. Additionally, the ACA amended the intent requirement of certain of these criminal statutes under HIPAA so that a person or entity no longer needs to have actual knowledge of the statute, or the specific intent to violate it, to have committed a violation; and
- State and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers and drug pricing and/or marketing expenditures; and state and local laws requiring the registration of pharmaceutical sales representatives and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Further, we may be subject to data privacy and security regulation by both the federal government and the states and foreign jurisdictions in which we conduct our business. HIPAA, as amended by the Health Information Technology for Clinical Health Act of 2009 ("HITECH"), and its respective implementing regulations imposes certain requirements, including mandatory contractual terms, on covered entities, business associates and their covered subcontractors relating to the privacy, security, and transmission of certain individually identifiable health information known as protected health information. Among other things, HITECH, through its implementing regulations, makes HIPAA's security standards and certain privacy standards directly applicable to business associates, defined as a person or organization, other than a member of a covered entity's workforce, that creates, receives, maintains, or transmits protected health information on behalf of a covered entity for a function or activity regulated by HIPAA. HITECH also strengthened the civil and criminal penalties that may be imposed against covered entities, business associates, subcontractors, and individuals, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, other federal and state laws may govern the privacy and security of health and other information in certain circumstances, many of which differ from each other in significant ways and may not be pre-empted by HIPAA, thus complicating compliance efforts.

To the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

In the EU, the data privacy laws are generally perceived to be stricter than those that apply in the U.S. and include specific requirements for the transfer of personal data outside the EU to the U.S. to ensure that EU standards of data privacy will be applied to such data.

Violation of the laws described above or any other governmental laws and regulations may result in significant penalties, including administrative, civil and criminal penalties, damages, fines, the curtailment or restructuring of operations, the exclusion from participation in federal and state healthcare programs, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, imprisonment, and additional reporting requirements and oversight if a person becomes subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws. Furthermore, efforts to ensure that business activities and

business arrangements comply with applicable healthcare laws and regulations can be costly for manufacturers of branded prescription products.

Health Reform

The U.S. and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the U.S. and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. In the U.S., the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by federal and state legislative initiatives, including those designed to limit the pricing, coverage, and reimbursement of pharmaceutical products, especially under government-funded health care programs, and increased governmental control of drug pricing.

By way of example, in March 2010, the ACA was signed into law, intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose taxes and fees on the healthcare industry and impose additional health policy reforms. The ACA contains a number of provisions of particular import to the pharmaceutical industry, including those governing enrollment in federal healthcare programs, reimbursement adjustments, and fraud and abuse changes. For example, the ACA requires collection of Medicaid rebates paid for covered outpatient drugs paid by Medicaid managed care organizations; imposes a nondeductible annual fee on pharmaceutical manufacturers or importers who sell "branded prescription drugs" to specified federal government programs; and requires a distinct calculation of rebates owed by manufacturers under the Medicaid Drug Rebate Program for covered outpatient drugs that are inhaled, infused, instilled, implanted, or injected.

The ACA and its implementation continue to evolve as a result of legislative, administrative, and judicial developments. We expect to continue to see changes involving the ACA which may potentially impact pricing, coverage, or reimbursement of our products.

In addition to the ACA, U.S. governments continue to seek to adopt healthcare policies and reforms intended to curb healthcare costs, such as federal or state controls on payment for drugs (including under Medicare, Medicaid, and commercial health plans). For example, the IRA, among other things, requires the U.S. Secretary of Health and Human Services to negotiate, with respect to Medicare units and subject to a specified cap, the price of a set number of certain high Medicare spend drugs and biologicals per year, with negotiated prices taking effect in 2026. The Inflation Reduction Act of 2022 ("IRA") also makes several changes to the Medicare Part D benefit, including an updated limit on annual out-of-pocket costs, a change in manufacturer liability under the program which could negatively affect our business and financial condition, and sunset of the existing coverage gap and coverage gap discount program,. The IRA also establishes a Medicare Part B and Part D inflation rebate scheme, under which manufacturers will owe rebates if, generally speaking, the average sales price of a Part B drug, or the annualized average manufacturer price of a Part D drug, increases faster than the pace of inflation.

Other legislative changes have been proposed and adopted in the U.S. since the ACA. For example, On January 20, 2025, the President of the United States signed an executive order creating an advisory commission, the "Department of Government Efficiency," to reform federal government processes and reduce expenditures. There have been widespread layoffs across various governmental agencies, including at the FDA, and other employees, including senior leaders at certain agencies, have resigned in response to the reforms, the full impact of which is unclear at this time. In addition, there is uncertainty around the funding, functioning and policy priorities of various governmental agencies, including the FDA. Disruptions or changes in how the FDA operates due to these policies could result in delays in FDA review or approval of product candidate applications. Further, applications for product candidates could fail to receive regulatory approval, or could be delayed in receiving regulatory approval. If federal spending is further reduced, anticipated budgetary shortfalls may also impact the ability of relevant agencies, such as the FDA or the National Institutes of Health, to continue to function at current levels. Amounts allocated to federal grants and contracts may be reduced or eliminated. These reductions may also impact the ability of relevant agencies to timely review and approve research and development, manufacturing, and marketing activities, which may delay our ability to develop, market and sell any products we may develop.

Under the current presidential administration, there have been significant and wide-ranging reforms to federal policy and the federal government, with drug pricing a particular area of focus. For example, President of the United States issued an Executive Order in April 2025 with multiple directives aimed at lowering drug prices, including refining

the Medicare drug price negotiation program established by the IRA; accelerating competition for high-cost prescription drugs by accelerating approval of generics and biosimilars and facilitating the process for re-classifying prescription drugs as over-the-counter drugs; and increasing drug importation. As another example, in May 2025, The President of the United States issued another Executive Order that directed government agencies and officials to identify most-favored nation pricing targets for prescription drugs (and looked to pharmaceutical manufacturers to make significant progress towards delivering target prices to patients); prevent foreign countries from disproportionately shifting the cost of global pharmaceutical research and development to the U.S.; and facilitate direct-to-consumer purchasing programs for pharmaceutical manufacturers to sell their products to patients at the most-favored-nation price. Many of these reform initiatives will require additional legal and/or administrative action to implement. Other healthcare reform efforts or actions may affect access to healthcare coverage or the funding of health care benefits, although the full impact of such efforts or actions cannot be predicted. For example, the Congressional Budget Office has estimated that Medicaid provisions in the One Big Beautiful Bill Act, including restrictions in eligibility and funding for Medicaid, as well as changes to the healthcare marketplace, is expected to increase the number of uninsured. There is uncertainty regarding the nature or impact of any drug or broader healthcare reform proposed or implemented by the current presidential administration through executive or administrative action or by Congress, and the extent to which any such action will be subject to litigation or other challenges. It is unclear how any such healthcare reform measures will impact our business. Healthcare reforms and action taken by the healthcare industry in response could adversely affect reimbursement, competitive dynamics, and our business. We continue to monitor legislative reforms and assess their potential impact on our operations, but we cannot predict their ultimate effect on our business. Additionally, the current presidential administration may propose policy changes that create additional uncertainty for our business. These may include new price restrictions on products we sell to Medicare or other government purchasers, or other regulatory changes impacting reimbursement or competitive dynamics in multisource markets. At the state level, governments have and continue to consider and pass legislation and implement regulations designed to control pharmaceutical and biological product pricing. Some of these measures include restricting price, reimbursement, discounts, product access, and marketing; imposing drug price, cost, and marketing disclosure and transparency requirements; permitting importation from other countries; and encouraging bulk purchasing. Furthermore, a growing number of state attorneys general are filing legal challenges (including use of state antitrust laws) related to drug pricing and reimbursement against various supply chain entities such as pharmacy benefit managers, and such litigation could involve drug manufacturers to a greater degree in the future.

At the state level, individual states in the U.S. have increasingly passed legislation and implemented regulations designed to control pharmaceutical and therapeutic product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Some third-party payors also require pre-approval of coverage for new or innovative devices or therapies before they will reimburse healthcare providers that use such therapies.

We expect that these initiatives, as well as other healthcare reform measures that may be adopted in the future, as well as the trend toward managed healthcare and increasing influence of managed care organizations, may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors. The implementation of current and future cost containment measures or other healthcare reforms may adversely affect our operations and prevent us from being able to generate revenue, attain profitability or commercialize our product candidates.

Government Price Reporting

A number of government pricing programs create certain price reporting obligations. Under the Medicaid Drug Rebate program, a participating manufacturer is required to pay a rebate to each state Medicaid program for its covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by the state Medicaid program as a condition of having federal funds being made available for drugs under Medicaid and Medicare Part B. Those rebates are based on pricing data reported by the manufacturer on a monthly and quarterly basis to CMS.

Federal law requires that a manufacturer also participate in the 340B Drug Pricing program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B program requires participating manufacturers to agree to charge no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs to a specified "covered entities," including community health centers and other entities that receive

certain federal grants, as well as hospitals that serve a certain disproportionate share of low-income patients, among other requirements. The 340B ceiling price is calculated based on the information reported under the Medicaid Drug Rebate program.

Also under federal law, manufacturers must report to CMS, on a quarterly basis, average sales price information for certain categories of drugs that are paid under the Medicare Part B program. Manufacturers calculate average sales price based on a statutorily defined formula as well as regulations and guidance. CMS may use the reported information to determine payment rates for drugs under Medicare Part B.

In addition, manufacturers must pay refunds to Medicare for single source drugs or biologicals, or biosimilar biological products, reimbursed under Medicare Part B and packaged in single-dose containers or single-use packages for units of discarded drug reimbursed by Medicare Part B in excess of 10 percent of total allowed charges under Medicare Part B for that drug. A failure to pay refunds for discarded drugs under the discarded drug refund program could be subject us to civil monetary penalties of 125 percent of the refund amount.

Finally, in order to be eligible to have its products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by the Big Four agencies and certain federal grantees, a manufacturer is required to participate in the Veterans Affairs ("VA") Federal Supply Schedule ("FSS") pricing program, established under Section 603 of the Veterans Health Care Act of 1992. Under this program, the manufacturer is obligated to make its covered drugs available for procurement on an FSS contract and charge a price to the Big Four agencies that is no higher than the Federal Ceiling Price ("FCP"), which is a price calculated pursuant to a statutory formula. The FCP is derived from the Non-Federal Average Manufacturer Price ("Non-FAMP"), which the manufacturer calculates and reports to the VA on a quarterly and annual basis. Pursuant to applicable law, knowing provision of false information in connection with a Non-FAMP filing can subject a manufacturer to significant penalties for each item of false information. The FSS contract also contains extensive disclosure and certification requirements. Under Section 703 of the National Defense Authorization Act for FY 2008, the manufacturer is required to pay quarterly rebates to DoD on utilization of its innovator products that are dispensed through U.S. Department of Defense's Tricare network pharmacies to Tricare beneficiaries. The rebates are calculated as the difference between the annual Non-FAMP and FCP for the calendar year that the product was dispensed.

Data Privacy and Security

In the ordinary course of our business, we collect, process and store confidential and sensitive information, including personal information, intellectual property, trade secrets, and proprietary information owned or controlled by ourselves or other third parties. We, and third parties upon whom we rely, use sophisticated information technology, software and services to process, store, use, generate, transfer and disclose information, as well as other sensitive information controlled by ourselves or other third parties.

We may also be subject to federal, state, and foreign data privacy and security laws and regulations. In the U.S., numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws and regulations (e.g., Section 5 of the FTC Act), govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners, vendors, or other third parties on whom we rely. The legislative and regulatory framework related to the collection, use, retention, safeguarding, disclosure, sharing, transfer, security and other processing of personal data worldwide is rapidly evolving. The number and scope of data protection laws and regulations is changing, subject to differing applications and interpretations, and may be inconsistent among jurisdictions, or in conflict with other rules, laws or other data processing obligations. Efforts to ensure that our current and future business arrangements, including our relationship with our CROs or other vendors who process data on our behalf, comply with applicable data privacy and data security laws and regulations will involve substantial costs.

For example, HIPAA, as amended by HITECH, and its implementing regulations, impose requirements relating to the privacy, security and transmission of individually identifiable health information on certain health care providers, health plans and health care clearinghouses, known as covered entities, as well as their business associates and covered subcontractors that perform certain services that involve creating, receiving, maintaining or transmitting individually identifiable health information for or on behalf of such covered entities. Entities that are found to be in violation of HIPAA as the result of a breach of unsecured protected health information, a complaint about privacy practices or an audit by HHS, may be subject to significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective

action plan with HHS to settle allegations of HIPAA non-compliance. Further, entities that knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA covered entity in a manner that is not authorized or permitted by HIPAA may be subject to civil and criminal penalties. Even when HIPAA does not apply, according to the FTC, violating consumers' privacy rights or failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce in violation of Section 5 of the FTC Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards.

Likewise, we expect that there will continue to be new proposed laws, regulations and industry standards relating to privacy and data protection in the U.S., the EU and other jurisdictions, such as the California Consumer Privacy Act of 2018 ("CCPA"), which has been characterized as the first "GDPR-like" privacy statute to be enacted in the U.S. Although the CCPA exempts certain data processed in the context of clinical trials, the CCPA, to the extent applicable to our business and operations, may increase our compliance costs and potential liability with respect to the personal information we maintain about California residents. The CCPA among other effects, creates individual privacy rights for California consumers (as defined in the law), places increased privacy and security obligations on entities handling certain personal data of consumers or households, requires covered companies to provide disclosures to consumers regarding data collection, use and sharing practices, requires covered companies to allow users to opt-out of certain sales or transfers of personal information, and provides consumers with a private right of action for certain data breaches. The CCPA became effective on January 1, 2020, and the California Attorney General's authority to begin bringing enforcement actions began July 1, 2020. As currently written, the CCPA may impact our business activities and exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information. Further, the California Privacy Rights Act ("CPRA") was recently voted into law by California residents. The CPRA significantly amends the CCPA and imposes additional data protection obligations on covered companies doing business in California, including additional consumer rights processes and opt outs for certain uses of sensitive data. It also creates a new California data protection agency specifically tasked to enforce the law, which would likely result in increased regulatory scrutiny of California businesses in the areas of data protection and security. The substantive requirements for businesses subject to the CPRA went into effect on January 1, 2023. Other states, including Virginia, Colorado, Utah, New York, and Connecticut have enacted privacy laws similar to the CCPA. Moreover, other states such as Washington and Nevada have passed health privacy specific legislation.

We also are or will become subject to privacy laws in the jurisdictions in which we are established or in which we sell or market our products or run clinical trials. For example, in the EU, we are subject to Regulation (EU) 2016/679, the GDPR, in relation to our collection, control, processing, and other use of personal data (i.e. data relating to an identified or identifiable living individual). We process personal data in relation to participants in our clinical trials in the European Economic Area ("EEA"), including the health and medical information of these participants. The GDPR is directly applicable in each EU and EEA Member State, however, it provides that EU and EEA Member States may introduce further conditions, including limitations that could limit our ability to collect, use and share personal data (including health and medical information), or could cause our compliance costs to increase, ultimately having an adverse impact on our business. As noted above, the GDPR imposes onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and implement policies as part of its mandated privacy governance framework. It also requires data controllers to be transparent and disclose to data subjects (in a concise, intelligible and easily accessible form) how their personal information is to be used, imposes limitations on retention of personal data; defines for the first time pseudonymized (i.e., key-coded) data; introduces mandatory data breach notification requirements; and sets higher standards for data controllers to demonstrate that they have obtained valid consent for certain data processing activities. We are also subject to EEA rules with respect to cross-border transfers of personal data outside of the EEA. As noted above, recent legal developments in the EU have created complexity and uncertainty regarding transfers of personal data from the EEA to the U.S., e.g. on July 16, 2020, the Court of Justice of the European Union ("CJEU"), invalidated the EU-U.S. Privacy Shield Framework, or the Privacy Shield, under which personal data could be transferred from the EEA to U.S. entities who had self-certified under the Privacy Shield scheme. While the CJEU upheld the adequacy of the standard contractual clauses (a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism, and potential alternative to the Privacy Shield), it made clear that reliance on them alone may not necessarily be sufficient in all circumstances. Use of the standard contractual clauses must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination

country, in particular applicable surveillance laws and rights of individuals and additional measures and/or contractual provisions may need to be put in place, however, the nature of these additional measures is currently uncertain. On June 4, 2021, the European Commission adopted new standard contractual clauses under the GDPR for data transfers from entities that are subject to the GDPR to transfer personal data outside of the EEA. The new standard contractual clauses impose additional obligations, including the obligation to conduct a transfer impact assessment and, depending on a party's role in the transfer, to implement additional security measures and to update internal privacy practices. If we elect to rely on the standard contractual clauses for data transfers, we may be required to incur significant time and resources to update our contractual arrangements and to comply with new obligations. Additionally, on September 8, 2020, the Swiss Data Protection Authority (the Federal Data Protection and Information Commissioner) concluded that the Swiss-U.S. Privacy Shield does not provide an adequate level of protection for personal data transfer from Switzerland to the U.S. pursuant to the Swiss Federal Act on Data Protection. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the standard contractual clauses cannot be used, and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

We are subject to the supervision of local data protection authorities in those EU jurisdictions where we are established or otherwise subject to the GDPR. Fines for certain breaches of the GDPR are significant: up to the greater of €20.0 million or 4% of total global annual turnover. Further, following the withdrawal of the United Kingdom from the EU on January 31, 2020, pursuant to the transitional arrangements agreed between the United Kingdom and the EU, we will have to comply with the GDPR and separately the GDPR as implemented in the United Kingdom, each regime having the ability to fine up to the greater of €20 million / £17 million or 4% of global turnover. Following December 31, 2020, and the expiry of the post-Brexit transitional arrangements between the United Kingdom and EU, although it is likely that the data protection obligations of the GDPR will continue to apply to UK-related processing of personal data in substantially unvaried form and fashion, for at least the short term thereafter, the relationship between the United Kingdom and the EU in relation to certain aspects of data protection law remains unclear. For example, it is not yet clear whether the United Kingdom will be the subject of a so-called adequacy decision of the European Commission, and it is therefore unclear how data transfers between EU/EEA Member States and the United Kingdom will be treated. Any changes relating to the UK and EU position regarding aspects of data protection law may lead to additional compliance costs and could increase our overall risk. In addition to the foregoing, a breach of the GDPR or other applicable privacy and data protection laws and regulations could result in regulatory investigations, reputational damage, orders to cease/change our use of data, enforcement notices, an inability to process personal data or to operate in certain jurisdictions, or potential civil claims including class action type litigation.

Moreover, we use third-party service providers and sub-processors to help us operate our business and engage in processing on our behalf. If we, our service providers, partners, or other relevant third-parties have experienced, or in the future experience, any security incident(s) that result in any data loss, deletion or destruction, unauthorized access to, loss of, unauthorized acquisition or disclosure of, or inadvertent exposure or disclosure of sensitive information, or compromise related to the security, confidentiality, integrity of our (or their) information technology, software, services, communications or data, it may result in a material adverse impact, including without limitation, regulatory investigations or enforcement actions, litigation, or an inability to process data in some jurisdictions. Furthermore, applicable data protection laws, privacy policies and data protection obligations may require us to notify relevant stakeholders of security breaches, including affected individuals, customers, and regulators. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could result in a material adverse impact, including without limitation, regulatory investigations or enforcement actions.

Additional U.S. Regulation

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservation and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern the use, handling and disposal of various biologic, chemical and radioactive substances used in, and wastes generated by, operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. Equivalent laws have been adopted in other countries that impose similar obligations.

U.S. Foreign Corrupt Practices Act

The U.S. Foreign Corrupt Practices Act ("FCPA") prohibits U.S. corporations and individuals from engaging in certain activities to obtain or retain business abroad or to influence a person working in an official capacity. It is illegal to pay, offer to pay or authorize the payment of anything of value, directly or indirectly, to any foreign government official, government staff member, official or employee of a public international organization, or a political party or political candidate for the purpose of influencing any act or decision of the foreign entity in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity. The scope of the FCPA includes interactions with healthcare professionals of foreign state-owned or affiliated hospitals, universities, or research institutions. The FCPA also obligates companies whose securities are listed in the U.S. to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. Activities that violate the FCPA, even if they occur wholly outside the U.S., can result in criminal and civil fines, imprisonment, disgorgement, oversight, and suspension and debarment from government contracts, and refusal of orders under existing government contracts. Equivalent laws have been adopted in other foreign countries that impose similar or arguably broader obligations.

Canadian Government Regulation and Product Approval

In Canada, our product candidates and our research and development activities are primarily regulated by the Food and Drugs Act and the rules and regulations thereunder, which are enforced by Health Canada (including its Biologic and Radio-pharmaceutical Drugs Directorate). Health Canada's regulatory process for review, approval and regulatory oversight of products is similar to the regulatory process conducted by the FDA. To initiate clinical testing of a drug candidate in human subjects in Canada, a Clinical Trial Application ("CTA") must be filed with and approved by Health Canada. In addition, all federally regulated trials must be approved and monitored by research ethics boards. The review boards study and approve study-related documents and monitor trial data.

Prior to being given market authorization for a drug product, a manufacturer must present substantive scientific evidence of a product's safety, efficacy and quality as required by the Food and Drugs Act (Canada) and its associated regulations, including the Food and Drug Regulations. This information is usually submitted in the form of a New Drug Submission ("NDS"). Health Canada reviews the submitted information, sometimes using external consultants and advisory committees, to evaluate the potential benefits and risks of a drug. If after the review, the conclusion is that the patient benefits outweigh the risks associated with the drug, the drug is issued a Drug Identification Number ("DIN"), followed by a Notice of Compliance ("NOC"), which permits the market authorization holder (i.e., the NOC and DIN holder) to market the drug in Canada. Drugs granted an NOC may be subject to additional post-market surveillance and reporting requirements.

The principal steps required for drug approval in Canada are as follows:

Preclinical Toxicology Studies

Non-clinical studies are conducted in vitro and in animals to evaluate pharmacokinetics, metabolism and possible toxic effects to provide evidence of the safety of the drug candidate prior to its administration to humans in clinical studies and throughout development. Such studies are conducted in accordance with applicable laws and GLP.

Initiation of Human Testing

In Canada, the process of conducting human clinical trials with a new drug cannot begin until a CTA has been submitted, and the required number of days has lapsed without objection from Health Canada. Similar regulations apply in Canada to a CTA as to an IND in the United States. If the CTA is deemed by Health Canada to be acceptable, a No Objection Letter is issued. A Not Satisfactory Notice will be issued by Health Canada if significant deficiencies are identified or if timely responses to information requested have not been received.

Clinical Trials

Similar regulations apply in Canada regarding clinical trials as in the U.S. In Canada, Research Ethics Boards, or REBs, instead of IRBs, are used to review and approve clinical trial plans. Clinical trials involve the administration of an investigational new drug to human subjects under the supervision of qualified investigators, in most cases a

physician, in accordance with current Good Clinical Practices, or cGCP, requirements, which include review and approval by REBs. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the trial procedures, the parameters to be used in monitoring safety and the efficacy criteria to be evaluated and a statistical analysis plan. Similar to in the U.S., human clinical trials for new drugs are typically conducted in three sequential phases, Phase 1, Phase 2 and Phase 3.

The manufacture of investigational drugs for the conduct of human clinical trials is subject to cGMP requirements. Investigational drugs and active pharmaceutical ingredients imported into Canada are also subject to regulation by Health Canada relating to their labeling and distribution. Progress reports detailing the results of the clinical trials must be submitted at least annually to Health Canada and the applicable REBs, and more frequently if serious adverse events occur. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, in Canada, Health Canada or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an REB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the REB's requirements or if the drug has been associated with unexpected serious harm to subjects. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group regularly reviews accumulated data and advises the study sponsor regarding the continuing safety of trial subjects, potential trial subjects and the continuing validity and scientific merit of the clinical trial. A sponsor may also suspend or terminate a clinical trial based on evolving business objectives or competitive climate.

New Drug Submission

Upon successful completion of Phase 3 clinical trials in Canada, the company sponsoring a new drug then assembles all the preclinical and clinical data and other testing relating to the product's pharmacology, chemistry, manufacture, and controls, and submits it to Health Canada as part of a New Drug Submission, or NDS. The NDS is then reviewed by Health Canada for approval to market the drug.

As part of the approval process, Health Canada will inspect the facility or the facilities at which the drug is manufactured. Health Canada will not approve the product unless compliance with cGMP is satisfactory and the NDS contains data that provide substantial evidence that the drug is safe and effective in the indication studied. In addition, before approving an NDS, Health Canada will typically inspect one or more clinical sites to assure compliance with GCP.

Even if Health Canada approves a product candidate, it may limit the approved indications for use of the product candidate, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms.

Subsidiaries

We have two wholly owned subsidiaries, Suzhou Neuralstem Biopharmaceutical Co., Ltd. ("Suzhou"), organized under the laws of the People's Republic of China, and LBS. Suzhou was established by Seneca to sponsor the non-GDP Phase 2 clinical trial of NSI-566 that was conducted between 2013 and 2016 in Beijing, China. As of December 31, 2025, Suzhou has no employees or other operations. We are currently in the process of dissolving the Suzhou subsidiary. Our other subsidiary is LBS, which is our operating entity.

Contingent Value Right

Immediately prior to the closing of the Seneca Merger, Seneca issued each share of its common stock held by Seneca stockholders of record, one contingent value right ("CVR"). The CVR entitled the holder (the "CVR Holder") to receive, pro rata with the other CVR Holders, 80% of the net proceeds, if any and subject to certain minimum distribution limitations ("CVR Payment Amount"), received from the sale or licensing of the intellectual property owned, licensed or controlled by Seneca immediately prior to the closing of the Seneca Merger (the "Legacy Technology"); provided however that the CVR Holders are only entitled to receive such CVR Payment Amount if the sale or licensing of such Legacy Technology occurred on or before October 27, 2022 ("Legacy Monetization"). Pursuant to the terms of the CVR agreement ("CVR Agreement"), CVR Holders entitlement to

receive CVR Payment Amounts expired on April 27, 2025. There were no CVR Payments made to any of the CVR Holders pursuant to the CVR Agreement.

NSI-189 – Exclusive License and Subsequent Exercise of Purchase Option

Prior to the Seneca Merger, Seneca exclusively licensed certain patents and technologies, including a sublicense covering a synthetic intermediate, of Seneca's NSI-189 assets (“189 License”), along with a purchase option through December 16, 2023 (“Purchase Option”). On October 22, 2021, Alto Neuroscience ("Alto") agreed to terms of an early exercise of the Purchase Option under the 189 License and entered into an asset transfer agreement ("ATA"). Alto is a U.S. based public, clinical-stage biopharmaceutical company with a mission to redefine psychiatry by leveraging neurobiology to develop personalized and highly effective treatment options.

Pursuant to the ATA, Alto will be required to pay us up to an aggregate of $4.5 million upon the achievement of certain development and regulatory approval milestones for NSI-189 (or a product containing or otherwise derived from NSI-189), which is now known as ALTO-100. If Alto sells or grants to a third party a license to the patents and other rights specific to ALTO-100 prior to the achievement of a specified clinical development milestone, Alto will be required to pay us a low-double digit percentage of any consideration received by Alto from such license or sale, provided that the maximum aggregate consideration Alto will be required to pay us under the ATA, including the upfront payment and all potential milestones and transaction-related payments, will not exceed $5.0 million.

On October 22, 2024, Alto announced that its Phase 2b study of ALTO-100 in patients with major depressive disorder (MDD) did not meet its primary endpoint. Notwithstanding, ALTO-100 is being evaluated as an adjunctive treatment in a Phase 2b study in bipolar depression with topline data expected in the second half of 2026. Upon the enrollment of a patient in a Phase 3 clinical trial of ALTO-100, if it occurs, a milestone payment of $1.5 million will be due to us from Alto under the ATA.

NSI-532.IGF-1

On October 27, 2022, we entered an agreement to license NSI-532.IGF-1 to the Regents of the University of Michigan ("University of Michigan") for maintaining NSI-532.IGF-1 cell lines, continued development, maintaining patent protection, and seeking licensees. We received no upfront fees for the license. NSI-532.IGF-1 is a pre-clinical cell therapy being investigated as a potential therapy for prevention and treatment of Alzheimer’s disease. The University of Michigan shall bear 100% of the costs for patent filing, prosecution, maintenance, and enforcement of the patent rights. We will receive 50% of net revenues received by the University of Michigan from the licensing of patent rights through the last-to-expire patent in patent rights, unless otherwise earlier terminated, less all reasonable and actual out-of-pocket costs incurred in the litigation of patent rights.

Human Capital Resources

Overview

As of March 18, 2026, we have 14 full-time employees and no part-time employees. Of the full-time employees, three employees are engaged in primarily research and development activities and five employees are primarily engaged in finance, corporate strategy and business development, and other general administrative functions. We engage a number of consultants to assist with finance, operations, human resources, legal, investor relations and information technology functions, as well as, to the extent needed, our clinical operations. We have no collective bargaining agreements with our employees, and we have not experienced any work stoppages.

We consider our relations with our employees to be good.

Compensation, Benefits, and Professional Development

Our compensation programs, including our equity incentive programs, are designed to align our employees' interests with the drivers of growth and stockholder returns by supporting achievement of our primary business goals. Our goal is to attract and retain employees whose talents, expertise, leadership, and contributions are expected to support and facilitate growth and drive long-term stockholder value. Consequently, we provide employee wages that we believe are competitive within our industry, and we regularly evaluate the effectiveness of our compensation and benefit programs against industry benchmarks. We seek to align our employees' interests with those of stockholders by linking annual changes in compensation to overall company performance, as well as each individual’s contribution to the results achieved. The emphasis on overall company performance is intended to align the

employee's financial interests with the interests of shareholders. We are also committed to providing comprehensive benefit options and it is our intention to offer benefits that will allow our employees and their families to live healthier and more secure lives. All employees are eligible for medical, dental, and vision insurance, paid and unpaid leaves, group life and personal accident insurance coverage as well as the option to participate in our 401(k) plan and supplemental group life and short-term disability coverage.

Corporate Information

The registrant was originally incorporated in 2001 in the State of Delaware under the name Neuralstem, Inc. In October of 2019, Neuralstem, Inc. changed its name to Seneca Biopharma, Inc. In April of 2021, we effected the Seneca Merger, whereby LBS became a wholly owned subsidiary of Seneca. In April of 2021, we changed our name from Seneca Biopharma, Inc. to Palisade Bio, Inc. We do not currently maintain a physical headquarters but maintain a mailing address at 4600 South Syracuse Street, Suite 900, Denver, Colorado, 80237. Our telephone number is (858) 704-4900 and our website address is www.palisadebio.com.

The information on our website is not incorporated by reference in this annual report on Form 10-K or in any other filings we make with the SEC. We make available on or through our website certain reports and amendments to those reports that we file with or furnish to the SEC in accordance with the Securities Exchange Act of 1934, as amended. These include our annual reports on Form 10-K, our quarterly reports on Form 10-Q, and our current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act. We make this information available on or through our website free of charge as soon as reasonably practicable after we electronically file the information with, or furnish it to, the SEC.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. We have described below a number of uncertainties and risks that, in addition to uncertainties and risks presented elsewhere in this Annual Report on Form 10-K, may adversely affect our business, operating results and financial condition. The uncertainties and risks enumerated below as well as those presented elsewhere in this Annual Report on Form 10-K should be considered carefully when evaluating us, our business and the value of our securities.

Risks Related to Our Development, Commercialization and Regulatory Approval of Our Product Candidates

Our business depends on the successful clinical development, regulatory approval, and commercialization of our lead asset PALI-2108.

On October 9, 2024, Health Canada approved our Canadian Clinical Trial Application ("CTA") to commence a Phase 1 clinical trial for PALI-2108 in Canada. On November 7, 2024, we commenced the Phase 1 clinical trial of PALI-2108. On May 27, 2025, we announced positive results from the SAD, MAD and FE cohorts in healthy volunteers and on August 7, 2025 and September 17, 2025, we announced positive results from the UC cohort portion of the study. The clinical study successfully met its primary endpoints of safety, tolerability, and PK. On October 16, 2025, we dosed our first patients in an exploratory Phase 1b cohort in FSCD while we complete longer-term chronic safety and toxicology studies. The exploratory Phase 1b cohort in FSCD evaluates the safety, tolerability, PK, and PD of once-daily oral dosing of PALI-2108 over a 14-day treatment period as well as tissue-level pharmacology and molecular responses using paired ileal biopsies and peripheral blood mononuclear cells.

Our success depends on the development and clinical success of PALI-2108, which is subject to a number of risks, including:

- the continued enforceability of our research collaboration and license agreement with Giiant;
- timely and successful completion of required clinical trials, which may be significantly slower or costlier than we anticipate and/or produces results that do not achieve the primary or secondary endpoints of the trial(s);
- our ability to develop and implement clinical trial designs and protocols;
- the successful initiation and completion of our current planned clinical trials and any additionally required preclinical studies, if any;
- our ability to retain third-party CROs on terms acceptable to us for the conduct and oversight of our current and anticipated clinical trials;
- our ability to fund the development costs related to PALI-2108's clinical development;
- the approval by the FDA, Health Canada, or other regulatory authorities to commence the marketing of our product candidates;
- the ability for us and third-parties, if applicable, to achieve and maintain compliance with our contractual obligations and applicable regulatory requirements;
- the ability of our contract manufacturers to manufacture sufficient supply of our product candidates to meet the required clinical trial supplies and any additional required preclinical studies;
- the ability of our contract manufacturers to remain in good standing with regulatory agencies and to develop, validate and maintain commercially viable manufacturing facilities and processes that are compliant with cGMP regulations;
- our ability to obtain favorable labeling for our product candidates through regulators that allows for successful commercialization;
- acceptance by physicians, insurers, payors, and patients of the beneficial quality, safety and efficacy of our product candidates, if approved, including relative to alternative and competing treatments;

- our ability to price our product candidates to recover our development costs and applicable milestone or royalty payments, and generate a satisfactory profit margin; and
- our ability and our applicable collaboration and licensing partners' ability to establish and enforce intellectual property rights related to our product candidates and technologies.

If we do not achieve one or more of these factors, many of which are beyond our control, in a timely manner or at all, we could experience significant delays or an inability to obtain regulatory approvals or commercialize our proposed product candidates. We must also complete a number of additional clinical trials prior to obtaining regulatory approval to commercialize our product candidates. Accordingly, we cannot make assurances that we will ever be able to generate sufficient revenue through the sale of any product candidates, if approved, to internally fund our business.

There are substantial risks in drug development, and, as a result, we may not be able to successfully develop any product candidate, including our lead clinical product candidate, PALI-2108.

We have commenced our clinical trials of PALI-2108 for the treatment of UC and CD. Drug development requires a significant amount of capital and can take a long time to reach commercial viability, if it can be achieved at all. During the development process, we may experience technological barriers that we may be unable to overcome. Further, certain underlying premises in our development programs have not been proven. Because of these and similar uncertainties, it is possible that our product candidates will not reach commercialization. If we are unable to successfully develop and commercialize our product candidates, including our lead clinical product candidate, PALI-2108, we will be unable to generate revenue or build a sustainable or profitable business.

We depend on our license agreement with Giiant to permit us to use patents and patent applications relating to PALI-2108. Termination of these rights or the failure to comply with our obligations under the license agreement could materially harm our business and prevent us from developing or commercializing PALI-2108, our lead clinical product candidate.

We are a party to the Giiant License Agreement under which we have been granted rights to patents and patent applications that are important to our business. We rely on this license agreement to be able to use various proprietary technologies that are material to our business, including patents, and patent applications that cover PALI-2108. Our rights to PALI-2108 are subject to the continuation of, and our compliance with, the terms of the Giiant License Agreement. If we fail to comply with any of our obligations under the Giiant License Agreement, Giiant may have the right to terminate the Giiant License agreement, in which event we would not be able to continue the development or our proposed commercialization of PALI-2108. Additionally, disputes may arise under the Giiant License Agreement regarding the intellectual property that is subject to such agreement. If disputes over intellectual property that we have licensed, or in the future may license, prevent or impair our ability to maintain any of our license agreements, including the Giiant License Agreement, on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates and technologies.

Clinical drug development is expensive, time-consuming and uncertain.

The clinical development of product candidates is very expensive, time-consuming, difficult to design and implement, and the outcomes are inherently uncertain. Most product candidates that commence clinical trials are never approved by regulatory authorities for commercialization and of those that are approved, many do not generate sufficient revenue to cover their costs of development. In addition, we, any partner with which we may collaborate, the FDA, Health Canada, or any similar regulatory authority, state and local agencies, counterpart agencies in foreign countries, or the applicable Institutional Review Board ("IRB") at our trial sites, may suspend, delay, require modifications to or terminate our clinical trials, once begun, at any time.

We are currently conducting a Phase 1 clinical trial of PALI-2108 in Canada, and the FDA or applicable foreign regulatory authorities may not accept data from such trials, or any other trial we conduct outside of the U.S.

We are conducting a Phase 1 clinical trial of PALI-2108 in Canada. However, we have not received approval from the FDA to commence any clinical trials in the U.S., and there is no guarantee that we will be able to obtain such approval in a timely manner, if at all. If our Phase 1 clinical trial is successful and we seek to initiate a Phase 2 clinical trial in the U.S, there is no certainty that the FDA will accept the data generated from our Canadian trial. The FDA's acceptance of foreign clinical data is subject to certain conditions, including whether the trial was conducted in accordance with good clinical practices ("GCP") and whether the FDA can validate the trial data

through on-site inspections or other means. Moreover, the FDA will assess whether the trial design, patient population, endpoints, and other factors meet the standards expected for clinical trials conducted within the U.S.

In addition, regulatory approval for clinical trials and eventual drug approval in the U.S. is a complex process, influenced by several factors, including:

- the adequacy and relevance of the Phase 1 trial data in supporting progression to Phase 2, as evaluated by the FDA;
- the ability of the trial to meet safety, efficacy, and other scientific requirements set by the FDA, which may differ from those of Health Canada;
- whether the foreign clinical trial was conducted under an FDA-recognized regulatory authority, and whether FDA oversight is possible through monitoring or inspection of clinical sites; and
- the FDA's consideration of the risk-benefit ratio for continuing clinical development in the U.S., particularly based on data from a non-U.S. population.

Furthermore, while the FDA does have the ability to approve drugs that have undergone clinical trials in foreign jurisdictions, including Canada, approval is generally contingent on demonstrating that the trial data align with FDA standards and regulatory expectations. It is also possible that we may be required to conduct additional trials in the U.S. to address any concerns regarding the applicability of the foreign trial data to the U.S. population or regulatory environment. There can be no assurance that we will successfully obtain FDA approval to initiate a Phase 2 clinical trial in the U.S.

We may find it difficult to enroll patients in our clinical trials, which could delay or prevent us from proceeding with clinical trials of our product candidates.

Identifying and qualifying subjects to participate in our current and anticipated future clinical trials is critical to our success. Our inability to enroll patients in our clinical trials on a timely basis could result in the trials being delayed or never completed.

Patient enrollment and trial completion are affected by numerous additional factors, including the:

- process for identifying patients;
- design of the trial protocol;
- eligibility and exclusion criteria;
- perceived risks and benefits of the product candidate under study;
- availability of competing therapies and clinical trials;
- severity of the disease under investigation;
- proximity and availability of clinical trial sites for prospective patients;
- ability to obtain and maintain patients' consents;
- risk that enrolled patients will drop out before completion of the clinical trial;
- patient referral practices of physicians; and,
- ability to monitor patients adequately during and after treatment.

If we have difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned, we may need to delay, limit or terminate ongoing or planned clinical trials, any of which would have an adverse effect on our business, financial condition, results of operations and prospects.

We expect that our operations and development of PALI-2108 will require more capital than we currently have, and we cannot guarantee when or if we will be able to secure such additional funding.

We have historically funded our operations and prior development efforts through the sale of our securities. We believe we currently have sufficient capital to fund our operations through major clinical development milestones including a Phase 2 primary efficacy readout of PALI-2108 for UC that is expected in the second half of 2027 and a

Phase 2 primary efficacy readout of PALI-2108 CD that is expected in 2028. Notwithstanding the foregoing, we may need to secure additional funding. If we are not able to obtain additional capital in the future or on acceptable terms, we may need to curtail our anticipated clinical trials as well as our operations.

Our product candidates, including our lead clinical product candidate, PALI-2108, may cause undesirable side effects or have other unexpected properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in post-approval regulatory action.

Unforeseen side effects from PALI-2108 could arise either during clinical development or, if approved, after it has been marketed. Undesirable side effects could cause us, any partners with which we may collaborate, or regulatory authorities to interrupt, extend, modify, delay or halt clinical trials and could result in a more restrictive or narrower label or the delay or denial of regulatory approval by Health Canada, or comparable regulatory authorities like the FDA.

Results of clinical trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, trials could be suspended or terminated, and Health Canada or comparable regulatory authorities, like the FDA, could order us to cease further development of or deny approval of a product candidate for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in product liability claims. Any of these occurrences may have an adverse material effect on our business, financial condition, operating results and prospects.

Additionally, if we or others identify undesirable side effects, or other previously unknown problems, caused by a product after obtaining regulatory approval, a number of potentially negative consequences could result, which could prevent us or our potential partners from achieving or maintaining market acceptance of the product and could substantially increase the costs of commercializing such product.

There can be no assurance that our product candidates will obtain regulatory approval.

The sale of human therapeutic products in the U.S. and foreign jurisdictions is subject to extensive and time-consuming regulatory approval, which requires, among other things:

- preclinical data required for the submission of an IND or CTA;
- controlled research and human clinical testing;
- establishment of the safety and efficacy of the proposed product candidate;
- government review and approval of a submission containing manufacturing, preclinical and clinical data; and
- adherence to cGMP regulations during production and storage.

PALI-2108 will require significant development, clinical testing, possibly additional preclinical studies, and the investment of significant funds to gain regulatory approval before it can be commercialized. Although we are conducting a Phase 1 clinical trial in Canada, there can be no assurances that we will gain regulatory approval from the FDA, or any other regulatory agency, to conduct our Phase 2 and/or Phase 3 clinical trials in the U.S., or other foreign jurisdictions. The results of our human clinical testing of PALI-2108 may not meet applicable regulatory requirements. If approved in a jurisdiction, PALI-2108 may also require the completion of post-market studies. The process of completing clinical testing and obtaining the required approvals is expected to take a number of years and require the use of substantial resources. Further, there can be no assurance that PALI-2108 will be shown to be safe and effective throughout our clinical trials or receive applicable regulatory approvals.

On June 28, 2024, the U.S. Supreme Court issued an opinion holding that courts reviewing agency action pursuant to the Administrative Procedure Act "must exercise their independent judgment" and "may not defer to an agency interpretation of the law simply because a statute is ambiguous." The decision will have a significant impact on how lower courts evaluate challenges to agency interpretations of law, including those by the FDA and other agencies with significant oversight of the biopharmaceutical industry. The new framework is likely to increase both the frequency of such challenges and their odds of success by eliminating one way in which the government previously prevailed in such cases. As a result, significant regulatory policies will be subject to increased litigation and judicial scrutiny.

If we fail to obtain regulatory approvals, or if there are significant changes in regulatory policies that result in increased litigation and judicial scrutiny leading to unexpected delays and increased cost, we may not be able to market PALI-2108 and our operations will be adversely affected.

If clinical studies of PALI-2108 do not yield successful results, we may discontinue the development of PALI-2108.

We must demonstrate that PALI-2108 is safe and efficacious in humans through extensive clinical testing. We may experience numerous unforeseen events during, or as a result of, the testing process that could delay or prevent commercialization of any products, including the following:

- the results of preclinical studies that we have completed may not be indicative of results that will be obtained in human clinical trials;
- safety and efficacy results attained in preclinical studies may not be indicative of results that are obtained in our clinical trials;
- after reviewing early clinical trial results, we may abandon projects that we previously believed to be promising;
- we or our regulators may suspend or terminate our clinical trials because the participating subjects or patients are being exposed to unacceptable health risks; and
- PALI-2108 may not have the desired effects or may include undesirable side effects or other characteristics that preclude regulatory approval or limit their commercial use if approved.

It may take us longer than we estimate to complete clinical trials, and we may not be able to complete them at all.

Although for planning purposes we project the commencement, continuation and completion of our clinical trials; a number of factors, including scheduling conflicts with participating researchers and/or CROs, clinicians and research or clinical institutions, and difficulties in identifying or enrolling patients who meet trial eligibility criteria, may cause significant delays. Even if we were to commence and complete our clinical trials involving PALI-2108 as currently contemplated, they may not be successful.

Even if PALI-2108 is approved for commercialization, future regulatory reviews or inspections may result in its suspension or withdrawal, closure of a facility or substantial fines.

If regulatory approval to market and commercialize PALI-2108 is received, regulatory agencies will subject PALI-2108, as well as the manufacturing facilities, to continual review and periodic inspection. If previously unknown problems with a product or manufacturing and laboratory facility are discovered, or we fail to comply with applicable regulatory approval requirements, a regulatory agency may impose restrictions on PALI-2108 or us. The agency may require the withdrawal of PALI-2108 from the market, closure of the facility or substantial fines.

The successful commercialization of PALI-2108, if approved, will depend in part on the extent to which government authorities and health insurers establish adequate reimbursement levels and pricing policies.

Sales of any approved drug candidate will depend in part on the availability of coverage and reimbursement from third-party payers such as government insurance programs in the applicable jurisdiction, including, for example, Medicare and Medicaid in the U.S., private health insurers, health maintenance organizations and other health care related organizations, who are increasingly challenging the price of medical products and services. Accordingly, coverage and reimbursement may be uncertain. Adoption of any drug by the medical community may be limited if third-party payers will not offer coverage. Additionally, significant uncertainty exists as to the reimbursement status of newly approved drugs. Cost control initiatives may decrease coverage and payment levels for any drug and, in turn, the price that we will be able to charge and/or the volume of our sales. We are unable to predict all changes to the coverage or reimbursement methodologies that will be applied by private or government payers. Any denial of private or government payer coverage or inadequate reimbursement could harm our business or future revenues, if any. If we partner with third parties with respect to any of our product candidates, we may be reliant on that partner to obtain reimbursement from government and private payors for the drug, if approved, and any failure of that partner to establish adequate reimbursement could have a negative impact on our revenues and profitability.

In addition, both the federal and state governments in the U.S. and foreign governments continue to propose and pass new legislation, regulations, and policies affecting coverage and reimbursement rates, which are designed to contain

or reduce the cost of health care. Further federal and state proposals and healthcare reforms are likely, which could limit the prices that can be charged for the product candidates that we develop and may further limit our commercial opportunity. There may be future changes that result in reductions in potential coverage and reimbursement levels for our product candidates, if approved and commercialized, and we cannot predict the scope of any future changes or the impact that those changes would have on our operations.

If future reimbursement for PALI-2108, subject to approval, is substantially less than projected, or rebate obligations associated with them are substantially greater than expected, our future net revenue and profitability, if any, could be materially diminished.

We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability for a product candidate and we may need to limit our commercialization.

The use of our product candidates in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by clinical trial participants, consumers, health-care providers, pharmaceutical companies, or others selling our products. If we cannot successfully defend ourselves against these claims, we may incur substantial liabilities. Regardless of merit or eventual outcomes of such claims, product liability claims may result in:

- decreased demand for our product candidates;
- impairment of our business reputation;
- withdrawal of clinical trial participants;
- costs of litigation;
- substantial monetary awards to patients or other claimants; and
- loss of revenues.

Our insurance coverage may not be sufficient to reimburse us for all expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses.

Even if a product candidate obtains regulatory approval, it may fail to achieve the broad degree of physician and patient adoption and use necessary for commercial success.

The commercial success of our product candidates, if approved, will depend significantly on attaining broad adoption and use of the drug by physicians and patients. The degree and rate of physician and patient adoption of a product, if approved, will depend on a number of factors, including but not limited to:

- patient demand for approved products that treat the indication for which they are approved;
- the effectiveness of a product compared to other available therapies or treatment regimens;
- the availability of coverage and adequate reimbursement from managed care plans and other healthcare payors;
- the cost of treatment in relation to alternative treatments and willingness to pay on the part of patients;
- insurers' willingness to see the applicable indication as a disease worth treating;
- proper administration by physicians or patients;
- patient satisfaction with the results, administration and overall treatment experience;
- limitations or contraindications, warnings, precautions or approved indications for use different than those sought by us that are contained in the final approved labeling;
- any requirement of an authoritative regulatory body to undertake a risk evaluation and mitigation strategy;
- the effectiveness of our sales, marketing, pricing, reimbursement and access, government affairs, and distribution efforts;

- adverse publicity about a product or favorable publicity about competitive products;
- new government regulations and programs, including price controls and/or limits or prohibitions on ways to commercialize drugs, such as increased scrutiny on direct-to-consumer advertising of pharmaceuticals; and
- potential product liability claims or other product-related litigation.

If any of our product candidates are approved for use but fail to achieve the broad degree of physician and patient adoption necessary for commercial success, our operating results and financial condition will be adversely affected, which may delay, prevent or limit our ability to generate revenue and continue our business.

Risks Related to Healthcare Laws and Other Legal Compliance Matters

Recent and future changes in healthcare legislation and regulations may increase the difficulty and cost to obtain marketing approval for a drug candidate, increase the costs to commercialize an approved product, and adversely affect the price set for such product.

In the United States and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system that could impact the future results of our operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels with the stated objective to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, ACA was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers. The ACA and its implementation continue to evolve as a result of legislative, administrative, and judicial developments. Further changes remain possible, which may potentially negatively affect pricing, coverage, or reimbursement for any product candidates that we may commercialize in the future, including PALI-2108.

In addition to the ACA, U.S. governments continue to seek to adopt healthcare policies and reforms intended to curb healthcare costs, such as federal or state controls on payment for drugs (including under Medicare, Medicaid, and commercial health plans). For example, the Budget Control Act of 2011 resulted in aggregate reductions, or sequestration, of Medicare payments to providers. Sequestration is currently set at 2% and will increase to 2.25% for the first half of fiscal year 2030, to 3% for the second half of fiscal year 2030, and to 4% for the remainder of the sequestration period that lasts through the first six months of fiscal year 2031. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, adjusted Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

More recently, the IRA requires, among other things, the U.S. Secretary of the Department of HHS to negotiate, with respect to Medicare units and subject to a specified cap, the price of a set number of certain high spend Medicare Part B and D drugs and biologicals per year (the Maximum Fair Price), with prices taking effect starting in 2026. The IRA also makes several changes to the Medicare Part D benefit, including capping patient out-of-pocket spending at $2,000 beginning in 2025, subject to annual increases tied to aggregate Part D expenditures, while imposing new discount obligations for pharmaceutical manufacturers and payors (and sunsetting the coverage gap and coverage gap discount program), which could negatively affect our business and financial condition. If we are not in compliance with obligations under the Medicare Part D benefit redesign, we could be subject to civil monetary penalties. In addition, the IRA establishes Medicare Part B and Part D inflation rebate schemes, under which manufacturers will owe rebates to Medicare if, generally speaking, the average sales price of a Part B drug, or the annualized average manufacturer price of a Part D drug, increases faster than the pace of inflation. The failure to timely pay an inflation rebate may result in a civil monetary penalty. Since the IRA was enacted, the CMA has taken various steps to implement the drug pricing provisions of the law. This includes, on a quarterly basis, releasing a list of Medicare Part B products that had an adjusted coinsurance rate based on the inflationary rebate provisions of the IRA, as well as guidance and regulations governing the same issuing guidance detailing the requirements and parameters of the first rounds of price negotiations and effectuation of the Maximum Fair Price and negotiating the Maximum Fair Price for the first 10 drugs subject to negotiation and releasing the list of next 15 drugs. While it remains to be seen how the drug pricing provisions imposed by the IRA will affect the broader pharmaceutical industry (including orphan drug development), several pharmaceutical manufacturers and other industry stakeholders have challenged the law, including through lawsuits brought against federal agencies challenging the constitutionality and administrative implementation of the IRA's drug price negotiation provisions. The IRA and

any other similar laws introduced in the future may result in additional reductions in Medicare and other healthcare funding, which could negatively affect our future revenues and results of operations.

Individual states in the United States have also become increasingly aggressive in seeking to pass legislation and implementing regulations designed to control pharmaceutical and biological product pricing. Such measures could harm our business, results of operations, financial condition, and prospects. For example, an emerging trend at the state level is the establishment of prescription drug affordability boards, some of which will prospectively permit certain states to establish upper payment limits for drugs that the state has determined to be "high-cost". We expect that additional state reform measures will be adopted in the future, any of which could limit the amounts that state governments will pay for healthcare products and services, which could result in reduced demand or lower pricing for our product candidates, or additional pricing pressures.

In markets outside of the United States, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative action in the United States or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

Our business operations and current and future relationships with contractors, investigators, healthcare professionals, consultants, third-party payors, patient organizations, customers, and others will be subject to applicable healthcare regulatory laws, which could expose us to penalties.

Our business operations and current and future arrangements with contractors, investigators, healthcare professionals, consultants, third-party payors, patient organizations, and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell, and distribute our product candidates, as well as our customer support and physician consulting arrangements. Such laws include:

- the U.S. federal Anti-Kickback Statute, a criminal law which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving, or providing any remuneration (including any kickback, bribe, or anything of value), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order, arrangement, or recommendation of, any good, facility, item or service for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs (such as Medicare and Medicaid). A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers or their agents and prescribers, purchasers and formulary or benefit managers, among other parties;

- the U.S. federal false claims and civil monetary penalties laws, including the FCA, which prohibits any person from, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment of government funds; knowingly making, using or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the U.S. federal government. In addition, any claims submitted as a result of a violation of the Anti-Kickback Statute constitute false claims and are subject to enforcement under the FCA. Pharmaceutical manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The FCA can be enforced by the U.S. Department of Justice or through whistleblower or qui tam actions filed by private citizens on behalf of the federal government;

- certain criminal provisions enacted as part of HIPAA prohibit, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense, or knowingly and willfully making false statements relating to healthcare matters, regardless of the payor (e.g., public or private). Similar to the Anti-

Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- HIPAA and the respective implementing regulations, which impose, among other things, specified requirements relating to privacy, security and breaches of individually identifiable health information by covered entities subject to the rule, such as health plans, healthcare clearinghouses and healthcare providers as well as their business associates that perform certain services involving the creation, receipt, maintenance, or transmission of protected health information. HIPAA provides for criminal penalties, as well as civil monetary penalties, and is enforced by the Office of Civil Rights within the HHS as well as state attorneys general, which can file civil actions for damages or injunctions in federal courts and seek attorneys' fees and costs associated with pursuing federal civil actions;
- Under, section 5 of the Federal Trade Commission ("FTC") Act ("FTC Act"), the FTC expects a company's data privacy and security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Failure to meet these standards may constitute unfair or deceptive acts or practices in violation of the FTC Act. The FTC also has the power to enforce the Health Breach Notification Rule, which imposes notification obligations on companies for breaches of certain health information contained in personal health records;
- the FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics, and medical devices;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- the U.S. federal Physician Payments Sunshine Act, enacted as part of the ACA, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics, and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program, along with others, to track and report annually to the government information related to certain payments and other transfers of value to U.S.-licensed physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiology assistants certified nurse-midwives, and teaching hospitals, as well as ownership and investment interests held by certain physicians and their immediate family members in the manufacturer;
- the federal Civil Monetary Penalties Law, which authorizes the imposition of substantial monetary penalties against an entity, such as a pharmaceutical manufacturer, that engage in activities including, among others (1) knowingly presenting, or causing to be presented, a claim for services not provided as claimed or that is otherwise false or fraudulent in any way; (2) arranging for or contracting with an individual or entity that is excluded from participation in federal health care programs to provide items or services reimbursable by a federal health care program; (3) violations of the Anti-Kickback Statute; or (4) failing to report and return a known overpayment;
- analogous U.S. state laws and regulations, including: state anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information that require the tracking of gifts and other remuneration and items of value provided to healthcare professionals and entities; and state laws governing privacy, security, and breaches of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. For example, the CCPA, as amended by the CPRA, establishes certain requirements for data use and sharing transparency and provides California consumers (as defined in the law) certain rights concerning the use, disclosure, and retention of their personal data. Such rights include rights to access and delete personal information, opt out of certain personal information sharing, and receive detailed information about how personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches—involving certain types of personal information—that is

expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability. Numerous other states, such as Virginia, Colorado, Utah, New York, and Connecticut, have enacted privacy laws similar to the CCPA, and some states, like Washington and Nevada, have enacted health privacy specific laws that grant heightened rights with respect to health information;

- similar healthcare laws and regulations in the EU, and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers and laws governing the privacy and security of personal information, such as, where applicable, the General Data Protection Regulation, including as implemented in the UK, or GDPR, which imposes obligations and restrictions on the processing of personal data relating to individuals located in the EU and the European Economic Area ("EEA") (including health data); and
- laws and regulations prohibiting bribery and corruption such as the FCPA, which, among other things, prohibits U.S. companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations or foreign government-owned or affiliated entities, candidates for foreign public office, and foreign political parties or officials thereof.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available under such laws, it is possible that some of our business activities, including our consulting agreements and other relationships with healthcare providers, could be subject to challenge under one or more such laws. Ensuring that our current and future internal operations and business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance, or case law involving applicable fraud and abuse or other healthcare laws and regulations.

If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to actions including the imposition of civil, criminal, and administrative penalties, damages (potentially up to treble damages), disgorgement, monetary fines, exclusion from participation in Medicare, Medicaid, and other federal healthcare programs, individual imprisonment, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements, or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Further, defending against any such actions can be costly, time consuming, and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be adversely affected.

We are subject to environmental, health and safety laws and regulations, and we may become exposed to liability and substantial expenses in connection with environmental compliance or remediation activities.

Our operations, including our development, testing and manufacturing activities, are subject to numerous environmental, health and safety laws and regulations. These laws and regulations govern, among other things, the controlled use, handling, release, and disposal of and the maintenance of a registry for, hazardous materials and biological materials, such as chemical solvents, human cells, carcinogenic compounds, mutagenic compounds, and compounds that have a toxic effect on reproduction, laboratory procedures and exposure to blood-borne pathogens. If we fail to comply with such laws and regulations, we could be subject to fines or other sanctions.

As with other companies engaged in activities similar to ours, we face a risk of environmental liability inherent in our current and historical activities, including liability relating to releases of or exposure to hazardous or biological materials. Environmental, health and safety laws and regulations are becoming more stringent. We may be required to incur substantial expenses in connection with future environmental compliance or remediation activities, in which case, the production efforts of our third-party manufacturers or our development efforts may be interrupted or delayed.

We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations. We can face serious consequences for violations.

U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations, which we collectively refer to as Trade Laws, prohibit, among other things, companies and their

employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Exports of our products are further subject to export controls and sanctions laws and regulations imposed by the U.S. government and administered by the U.S. Departments of State, Commerce, and Treasury. U.S. export control laws may require a license or other authorization to export products to certain destinations and end users. In addition, U.S. economic sanctions laws include restrictions or prohibitions on engaging in any transactions or dealings, including receiving investment or financing from, or engaging in the sale or supply of products and services to, U.S. sanctioned countries, governments, persons and entities.

Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We also expect our non-U.S. activities to increase over time. We expect to rely on third parties for research, preclinical studies, and clinical trials and/or to obtain necessary permits, licenses, patent registrations, and other marketing approvals. We can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities. Any changes in Trade Laws could result in a decreased ability to export or sell our solutions to existing or potential customers with international operations. Future changes in Trade Laws and enforcement could also result in increased compliance requirements and related costs which could materially adversely affect our business, results of operations, financial condition and/or cash flows.

Risks Related to Our Business

We have a limited operating history and have never generated any revenues from product sales.

We are a biopharmaceutical company with a limited operating history that may make it difficult to evaluate the success of our business and to assess our future viability. While we were initially formed in 2001, our operations have historically been limited to business planning, raising capital and other research and development activities related to our product candidates. We have never completed the development of any product candidate through to commercialization, nor have we ever generated any revenue from product sales. Consequently, we have no meaningful operations upon which to evaluate our business, and predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing biopharmaceutical products.

Our business model assumes revenue from, among other activities, marketing or out-licensing the products we develop. PALI-2108 is in the early stages of clinical development and because we have a short development history with PALI-2108, there is a limited amount of information about us upon which you can evaluate our business and prospects.

We have no approved drugs and thus have not begun to market or generate revenues from the commercialization of any products. We only have a limited history upon which we can evaluate our ability to develop PALI-2108. We commenced our initial Phase 1 clinical trial of PALI-2108 in November of 2024. While we have announced positive results from the SAD, MAD and FE cohorts in healthy volunteers, as well as the UC cohort portion of the study, and have dosed patients in an exploratory Phase 1b cohort in FSCD, we have limited experience and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical area.

For example, to execute our business plan, we will need to:

- execute product development activities using unproven technologies;
- build, maintain, and protect a strong intellectual property portfolio;
- demonstrate safety and efficacy of our product candidates in multiple human clinical studies;
- receive approval from the FDA and/or approval from similar foreign regulatory bodies;
- retain qualified CROs to oversee and manage the continued development of PALI-2108 through current and future clinical trials;
- gain market acceptance for the development and commercialization of any drugs we develop;

- ensure our products are reimbursed by commercial and/or government payors at a rate that permits commercial viability;
- develop and maintain successful strategic relationships with suppliers, distributors, and commercial licensing partners;
- manage our spending and cash requirements as our expenses will increase in the near term if we add programs and additional preclinical and clinical trials; and
- effectively market any products for which we obtain marketing approval.

If we are unsuccessful in accomplishing these objectives, we may not be able to develop our proposed products, raise capital, expand our business or continue our operations.

Our success depends on attracting and retaining senior management and scientists with relevant expertise.

Our future success depends to a significant extent on the continued services of our key employees, including our senior scientific, technical and managerial personnel. We do not maintain key person life insurance for any of our executives. Competition for qualified employees in the pharmaceutical industry is high, and our ability to execute our strategy will depend in part on our ability to continue to attract and retain qualified scientists and management. If we are unable to find, hire, and retain qualified individuals, we may be unable to execute our business plan in a timely manner, if at all.

We may choose to discontinue the development or commercialization any of our product candidates, or may choose not to commercialize product candidates in approved indications, at any time during development or after approval, which could adversely affect us and our operations.

At any time, we may decide to discontinue the development of, or temporarily pause the development of, any of our product candidates then in existence for a variety of reasons, including the appearance of new technologies that make our product candidates obsolete, competition from competing product(s) or changes in or failure to comply with applicable regulatory requirements. If we temporarily pause or terminate a program in which we have invested significant resources, we will not receive any return on our investment and we will have missed the opportunity to have allocated those resources to potentially more productive uses, which could have an adverse effect on us and our business.

Our inability to successfully in-license, acquire, develop and market additional product candidates or approved products could impair our ability to grow our business.

PALI-2108 is currently our only product candidate being actively developed. We may in-license, acquire, develop and market additional products and product candidates. Since our internal research and development capabilities are limited, we may be dependent on pharmaceutical companies, academic or government scientists and other researchers to sell or license products or technology to us. The success of this strategy depends partly on our ability to identify and select promising pharmaceutical product candidates and approved products, negotiate licensing or acquisition agreements with their current owners, and finance these arrangements.

The process of identifying, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing, sales and other resources, may compete with us for the license or acquisition of product candidates and approved products. Moreover, we may devote resources to potential acquisitions or licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional approved products or product candidates on terms that we find acceptable, or at all.

Further, any product candidate that we acquire or license may require additional development efforts prior to commercial sale, including preclinical or clinical testing and approval by the applicable regulatory authorities. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot provide assurance that any approved products that we acquire will be manufactured or sold profitably or achieve market acceptance.

Changes in funding for the FDA and, other government agencies or comparable foreign regulatory authorities could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent these agencies or authorities from performing normal business functions on which the operations of our business may rely, which could negatively impact our business.

The ability of the FDA or comparable foreign regulatory authorities to review and approve new products, to provide feedback on clinical trials and development programs, to meet with sponsors and to otherwise review regulatory submissions can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key leadership and other personnel, the sufficiency of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies or comparable foreign regulatory authorities on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other government agencies or comparable foreign regulatory authorities may also slow the time necessary for new drugs to be reviewed or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times, including recently from October 1, 2025 through November 12, 2025, and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical employees from the FDA, SEC, and other government offices, halting critical activities. If another prolonged government shutdown occurs, it could significantly impact the ability of the FDA and other governmental agencies to review and process our regulatory submissions in a timely manner, which could have a material adverse effect on our business. Furthermore, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Risks Related to Our Dependence on Third Parties

We currently rely on and we intend to continue relying on third-party CROs and other third parties to conduct and oversee our clinical trials. If these third parties do not meet our requirements or otherwise conduct the trials as required, we may not be able to satisfy our contractual obligations for, obtain regulatory approval for, or commercialize our product candidates.

We have retained a CRO to oversee our Phase 1 clinical trial for PALI-2108 in Canada. We intend to rely on third-party CROs to conduct and oversee our other anticipated clinical trials and other aspects of product development. We also expect to rely on various medical institutions, clinical investigators and contract laboratories to conduct our trials in accordance with our clinical protocols and all applicable regulatory requirements, including the FDA's regulations and GCP requirements, which are an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors, and state regulations governing the handling, storage, security and recordkeeping for drug and biologic products. These CROs and other third parties are expected to play a significant role in the conduct of these trials and the subsequent collection and analysis of data from the clinical trials. We expect to rely heavily on these parties for the execution of our clinical trials and any additionally required preclinical studies and will control only certain aspects of their activities. We and our CROs and other third-party contractors will be required to comply with GCP and GLP regulations, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities, such as Health Canada, with respect to our Phase 1 clinical trial for PALI-2108. Regulatory authorities enforce these GCP or GLP regulations through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP and GLP regulations, or reveal noncompliance from an audit or inspection, any clinical data generated in our clinical trials may be deemed unreliable, and the FDA or other regulatory authorities may require us to perform additional clinical trials before approving our or our partners' marketing applications. We cannot assure that upon inspection by a given regulatory authority such regulatory authority will determine whether any of our clinical trials comply with applicable GCP or GLP regulations. In addition, our clinical trials generally must be conducted with compounds produced under cGMP regulations. Our failure to comply with these regulations and policies may require us to repeat clinical trials, which would be costly and delay the regulatory approval process. In the event that we are unable to retain a qualified CRO for any of our anticipated clinical trials, it would delay planned clinical operations and result in additional cost and expense. Additionally, if our current CRO for our Phase 1 clinical trial in Canada or if any of our CROs that we retain in the future were to terminate their involvement with

us, there is no assurance that we would be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms.

In addition, foreign CMOs may be subject to U.S. legislation, sanctions, trade restrictions and other foreign regulatory requirements which could increase the cost or reduce the supply of material available to us, delay the procurement or supply of such material or have an adverse effect on our ability to secure significant commitments from governments to purchase our potential therapies. For example, the BIOSECURE Act was recently enacted, which prohibits U.S. federal agencies from entering into or renewing a contract with any company that uses biotechnology equipment or services produced or provided by a "biotechnology company of concern" in the performance of that contract. It would also prohibit loans or grant funding from U.S. federal agencies to entities that use any biotechnology equipment or services produced or provided by a "biotechnology company of concern" in the performance of the government grant or loan. The BIOSECURE Act restricts the ability of pharmaceutical companies that enter into contracts with or receive funding from U.S. federal agencies from purchasing certain services or equipment from certain Chinese biotechnology companies. The BIOSECURE Act does not specifically name WuXi AppTec, our current CMO for the manufacture and supply of API for PALI-2108, or Crystal Formulation Services, our drug product vendor, as "biotechnology companies of concern." However, the Act provides a mechanism for Chinese companies to be designated as a "biotechnology company of concern" in the future, and it is possible that WuXi AppTec and/or Crystal Formulation Services could receive that designation in the future, which means we could be potentially restricted from pursuing U.S. federal government business for our products in the future if we continue to use WuXi AppTec, Crystal Formulation Services or other suppliers or partners identified as "biotechnology companies of concern." In addition to the BIOSECURE Act, any additional executive action, legislative action, or potential sanctions with China could materially impact our work with these Chinese companies. U.S. executive agencies have the ability to designate entities and individuals on various governmental prohibited and restricted parties lists. Depending on the designation, potential consequences can range from a comprehensive prohibition on all transactions or dealings with designated parties, or a limited prohibition on certain types of activities, such as exports and financing activities, with designated parties.

We depend on two qualified suppliers for the active pharmaceutical ingredient used in the clinical trials of PALI-2108. Insufficient availability of the API or other raw materials necessary to manufacture PALI-2108, or the inability of our suppliers to manufacture and supply our products on commercially reasonable terms, could adversely impact our business, results of operations and financial condition.

We have two qualified suppliers for the API used in PALI-2108. We do not have, and we do not intend to establish in the foreseeable future, internal manufacturing capabilities. Instead, we intend to use the facilities of third-party manufacturers to produce the materials used in our clinical trials. Our dependence on third parties for the supply and manufacture of PALI-2108 and any future product candidates may adversely affect our ability to obtain our products in a timely or competitive manner, if at all.

Any supply shortages, quality concerns, or failure to obtain sufficient API, excipients, or components from our suppliers, including disruptions caused by, among other things, supply chain delays, public health emergencies, climate events, or political unrest would adversely affect our business, results of operations and financial condition. In particular, our suppliers may be impacted by epidemics, pandemics or other disease outbreaks or public health emergencies and general macroeconomic conditions, including inflationary pressures, economic slowdown or recession, relatively high interest rates, imposed tariffs, changes in monetary policy, potential U.S. federal government shutdowns, geopolitical conflicts and financial institution instability, all of which may result in supply delays and cost increases.

The manufacturing process for pharmaceutical products is highly regulated, and regulatory agencies may from time to time shut down facilities that they believe do not comply with regulations. Our third-party manufacturers and suppliers are subject to numerous FDA and Health Canada regulations, including those governing manufacturing processes, stability testing, record keeping, product serialization, and quality standards. Similar regulations apply in other jurisdictions where we may conduct business. Our third-party manufacturers and suppliers are independent entities who are subject to their own operational and financial risks which are out of our control.

If we, our third-party manufacturers, or our suppliers fail to comply with these regulations, our ability to deliver adequate supplies of PALI-2108 for clinical trials in a timely and cost-effective manner may be adversely affected. Should any of these risks materialize and adversely affect such third-party manufacturers' and/or suppliers' performance obligations to us, and we are unable to secure sufficient of the API used in the manufacture of PALI-2108 on commercially acceptable terms, or if we encounter delays and difficulties in our relationships with manufacturers or suppliers, our business, results of operations and financial condition could be adversely affected.

We expect to rely on collaborations with third parties for the successful development and commercialization of our product candidates.

We currently rely on and expect to continue to rely upon the efforts of third parties for the successful development and commercialization of our product candidates. The clinical and commercial success of our product candidates may depend upon maintaining successful relationships with third-party partners, which are subject to a number of significant risks, including the following:

- our partners' ability to execute their responsibilities in a timely, cost-efficient and compliant manner;
- reduced control over delivery and manufacturing schedules;
- price increases;
- manufacturing deviations from internal or regulatory specifications;
- quality incidents;
- the failure of partners to perform their obligations for technical, market or other reasons;
- misappropriation of our product candidates; and
- other risks in potentially meeting our product commercialization schedule or satisfying the requirements of our end-users.

We cannot provide any assurance that we will be able to establish or maintain third-party relationships in order to successfully develop and commercialize our product candidates.

We currently rely on third-party contractors to supply, manufacture and distribute clinical drug supplies for our product candidates.

We do not currently have, nor do we currently plan to acquire, the infrastructure or capability to supply, store, manufacture or distribute clinical or commercial quantities of drug substances or products. Although we have entered into a supply agreement to provide us with such drug substances or products for our current Phase 1 clinical trial, our future ability to develop and commercialize, if approved, our product candidates is dependent on our ability to obtain the APIs and other substances and materials used in our product candidates successfully from third parties and to have finished products manufactured by third parties in accordance with regulatory requirements and in sufficient quantities for preclinical and clinical testing and commercialization. If we fail to develop and maintain supply and other technical relationships with these third parties, we may be unable to continue to develop or commercialize our products and product candidates, which could adversely affect us and our business.

We are dependent on our contract suppliers and manufacturers for day-to-day compliance with applicable laws and cGMP regulations for production of our proposed products and API. If the safety or quality of any product or product candidate or component is compromised due to a failure to adhere to applicable laws or for other reasons, we may not be able to commercialize or obtain regulatory approval for the affected product or product candidates successfully, and we may be held liable as a result.

We expect to continue to depend on third-party contract suppliers and manufacturers. Our supply and manufacturing agreements do not guarantee that a contract supplier or manufacturer will provide services adequate for our needs. Additionally, any damage to or destruction of our third-party manufacturers' or suppliers' facilities or equipment, even by force majeure, may significantly impair our ability to have our products and product candidates manufactured on a timely basis. Our reliance on contract manufacturers and suppliers further exposes us to the possibility that they, or third parties with access to their facilities, may misappropriate our trade secrets or other proprietary information. Furthermore, the manufacturing facilities of our suppliers are located outside of the U.S.

This may give rise to difficulties in importing our products or product candidates or their components into the U.S. or other countries.

We currently have agreements in place with foreign third parties in China and other countries to provide the necessary clinical supply of our API. Termination of or limitations on our relationships with foreign third parties that manufacture the API used in PALI-2108 may arise if U.S. legislation, tariffs, sanctions, trade restrictions, or other U.S. and foreign regulatory requirements, or prohibitions restrict our ability to engage with these foreign third parties. Further, any such actions could adversely impact our current and future arrangements with our foreign suppliers, including our current Chinese drug manufacturer, which could increase the cost or reduce the supply of material available to us or delay the procurement or supply of such material used in our clinical trial.

Risks Related to Our Financial Operations

We have a history of net operating losses, and we expect to continue to incur net operating losses and may never achieve profitability.

We have incurred net operating losses since our inception. We expect that our operating losses will continue for the foreseeable future as we continue our drug development and discovery efforts. To achieve profitability, we must, either directly or through licensing and/or partnering relationships, meet certain milestones, successfully develop and obtain regulatory approval for one or more product candidates and effectively manufacture, market and sell any drugs we successfully develop. Even if we are able to successfully commercialize product candidates that receive regulatory approval, we may not be able to realize revenues at a level that would allow us to achieve or sustain profitability. Accordingly, we may never generate significant revenue and, even if we generate significant revenue, we may never achieve profitability.

Failure to remediate a material weakness in internal controls over financial reporting could result in material misstatements in our consolidated financial statements.

Our management has identified a material weakness in our internal control over financial reporting. The material weakness was due to a lack of controls in the financial closing and reporting process, including a lack of segregation of duties and the documentation and design of formalized processes and procedures surrounding the creation and posting of journal entries and account reconciliations.

If our remaining material weakness, which management concluded is still present as of the date of these financial statements, is not remediated, or if we identify further material weaknesses in our internal controls, our failure to establish and maintain effective disclosure controls and procedures and internal control over financial reporting could result in material misstatements in our consolidated financial statements and a failure to meet our reporting and financial obligations.

Risks Related to Our Intellectual Property

We may not be able to obtain, maintain or enforce global patent rights or other intellectual property rights that cover our product candidates and technologies that are of sufficient breadth to prevent third parties from competing against us.

Our success with respect to our current and future product candidates will depend, in part, on our ability to obtain and maintain patent protection in both the U.S. and other countries, to preserve our trade secrets and to prevent third parties from infringing on our proprietary rights. Our ability to protect our product candidates from unauthorized or infringing use by third parties depends in substantial part on our ability to obtain and maintain valid and enforceable patents in certain countries.

The patent application process, also known as patent prosecution, is expensive and time-consuming, and we and our current or future licensors and licensees may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner in all the countries that are desirable. It is also possible that we or our current, or future licensors and licensees will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, these and any of our patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Moreover, our competitors independently may develop equivalent knowledge, methods and know-how or discover workarounds to our patents that would not constitute infringement. Any of these outcomes could impair our ability to enforce the exclusivity of any issued or pending patents we may

have or the ability to obtain future patent protections, which may have an adverse impact on our business, financial condition and operating results.

Our ability to obtain, maintain and/or enforce patents is uncertain and involves complex legal and factual questions, especially across varying countries. Accordingly, rights under any existing patents or any patents we might obtain or license may not cover our product candidates or may not provide us with sufficient protection for our product candidates to afford a sustainable commercial advantage against competitive products or processes, including those from branded, generic and over-the-counter pharmaceutical companies. In addition, we cannot guarantee that any patents or other intellectual property rights will be issued from any pending or future patent or other similar applications owned by or licensed to us. Even if patents or other intellectual property rights have issued or will issue, we cannot guarantee that the claims of these patents and other rights are or will be held valid or enforceable by the courts, through injunction or otherwise, or will provide us with any significant protection against competitive products or otherwise be commercially valuable to us in every country of commercial significance that we may target.

Our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and prior art make it patentable. We do not have outstanding issued patents covering all of the recent developments in our technology and we are unsure of the patent protection that we will be successful in obtaining, if any. Even if the patents are successfully issued, third parties may design around or challenge the validity, enforceability or scope of such issued patents or any other issued patents we own or license, which may result in such patents being narrowed, invalidated or held unenforceable. If the breadth or strength of protection provided by the patents we hold or pursue with respect to our product candidates are challenged, it could dissuade companies from collaborating with us to develop or threaten our ability to commercialize or finance our product candidates.

The laws of some foreign jurisdictions do not provide intellectual property rights to the same extent or duration as in the U.S., and many companies have encountered significant difficulties in acquiring, maintaining, protecting, defending and especially enforcing such rights in foreign jurisdictions. If we encounter such difficulties in protecting or are otherwise precluded from effectively protecting our intellectual property in foreign jurisdictions, our business prospects could be substantially harmed, especially internationally.

Proprietary trade secrets and unpatented know-how are also very important to our business. Although we have taken steps to protect our trade secrets and unpatented know-how by entering into confidentiality agreements with third parties, and intellectual property assignment and protection agreements with officers, directors, employees, and certain consultants and advisors, there can be no assurance that such agreements will not be breached or enforced by courts, that we would have adequate remedies for any breach, including injunctive and other equitable relief, or that our trade secrets and unpatented know-how will not otherwise become known, inadvertently disclosed by us or our agents and representatives, or be independently discovered by our competitors. If our trade secrets are independently discovered, we would not be able to prevent their use and if we or our agents or representatives inadvertently disclose trade secrets and/or unpatented know-how, we may not be allowed to retrieve these trade secrets and/or unpatented know-how and maintain the exclusivity we previously held.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on our product candidates does not guarantee exclusivity. The requirements for patentability vary between countries, particularly developing nations. In addition, the laws of some countries do not protect intellectual property rights to the same extent as the laws of all other countries or jurisdictions, especially when it comes to granting use and other types of patents and what kind of enforcement rights will be allowed, especially injunctive relief in a civil infringement proceeding. Consequently, we may not be able to prevent third parties from using our inventions or even in launching an identical version of our product even if we hold a valid patent. Competitors may use our technologies in jurisdictions where we have not obtained patent protection, or they may produce copy products, and, further, may export otherwise infringing products to territories where we have patent protection but enforcement against such activities is inadequate or where we have no patents. These products could compete with ours, and our patents or other intellectual property rights may not prevent them from competing.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance and annuity fees on any issued patent are due to be paid to applicable patent agencies, which require compliance with a number of procedures, including certain documentary, fee payment and other similar provisions during the patent application process. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees in prescribed time periods, and failure to properly legalize and submit formal documents in the format and style the country requires. While an inadvertent lapse can, in many cases, be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction just for failure to know about and/or timely pay a prosecution fee. If we or our licensors fail to maintain the patents and patent applications covering our product candidates for any reason, our competitors might be able to enter the market, which would have an adverse effect on our business.

If we fail to comply with our obligations under our intellectual property license agreements, we could lose license rights that are important to our business.

The Giiant License Agreement pursuant to which we license PALI-2108, and other assets of Giiant, contains certain requirements related to diligence, milestone, royalty, insurance, expense reimbursement, and other obligations. If we fail to comply with these obligations, Giiant may have the ability to terminate the license, subject to certain requirements as more fully set forth in the Giiant License Agreement. If the license granted thereunder were to be terminated, our business, financial condition, operating results, and prospects would be materially adversely affected.

We may be subject to patent infringement claims, which could result in substantial costs and liabilities, and could prevent us from commercializing our potential products.

Because the intellectual property landscape in the fields in which we participate is rapidly evolving and interdisciplinary, it is difficult to conclusively assess our freedom to operate without infringing on third-party rights. If any patent infringement claims are brought against us, regardless of whether successful, we may incur significant expenses and divert the attention of our management and key personnel from other business concerns. This could negatively affect our results of operations and prospects. We cannot be certain that patents owned or licensed by us will not be challenged, potentially successfully, by others.

In addition, if our product candidates are found to infringe the intellectual property rights of third parties, these third parties may assert infringement claims against our customers, licensees and other parties with whom we have business relationships, and we may be required to indemnify those parties for any damages they suffer as a result of such claims. The claims may require us to initiate or defend protracted and costly litigation on behalf of customers, licensees, and other parties regardless of the merits of these claims. If any of these claims succeed, we may be forced to pay damages on behalf of those parties or may be required to obtain licenses for the products they use. If we cannot obtain all necessary licenses on commercially reasonable terms, we may be unable to continue selling such products.

We may be subject to claims that our officers, directors, employees, consultants or independent contractors have wrongfully used or disclosed to us alleged trade secrets of their former employers or their former or current customers.

As is common in the biotechnology and pharmaceutical industries, certain of our employees were formerly employed by other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Moreover, we engage the services of consultants to assist us in the development of our product candidates, many of whom were previously employed at, or may have previously been or are currently providing consulting services to, other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that our employees or consultants have inadvertently or otherwise wrongfully used or disclosed trade secrets or other proprietary information of their former employers or their former or current customers. Although we have no knowledge of any such claims being alleged, if such claims were to arise, litigation may be necessary to defend against any such claims. Even if we are successful in defending against any such claims, the related litigation could be protracted, expensive, a distraction to our management team, and not viewed favorably by investors and other third parties.

Other Risks Related to Our Securities

We will need to raise additional financing in the future to fund our operations, which may not be available to us on favorable terms or at all.

We have used and we intend to use the proceeds from our previous offerings and any future offerings, to, among other things, advance PALI-2108 through preclinical and clinical development and into INDs or their equivalent in foreign jurisdictions, fund our research and development activities, and for general working capital needs. We will require substantial additional capital to fund our operations and conduct the costly and time-consuming research and development and clinical work necessary to pursue regulatory approval of product candidates. Our future capital requirements will depend upon a number of factors, including: the number and timing of product candidates in the pipeline; progress with and results from preclinical testing and clinical trials; the ability to manufacture sufficient drug supplies to complete clinical trials or any additional preclinical studies required; the costs involved in preparing, filing, acquiring, prosecuting, maintaining and enforcing patent and other intellectual property claims; and the time and costs involved in obtaining regulatory approvals and favorable reimbursement or formulary acceptance. Raising additional capital may be costly or difficult to obtain, which could inhibit our ability to achieve our business objectives. Given our limited cash reserves and the significant amount of capital that we will likely need to fund our operations and business plan, our stockholders will likely experience significant dilution to their ownership interests. If we raise additional funds through public or private equity sales of our securities, the terms of these securities may include liquidation or other preferences that adversely impact the rights of our common stockholders. Further, to the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, our stockholders' ownership percentage will be decreased. In addition, any debt financing may subject us to fixed payment obligations and covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances, or licensing arrangements with third parties, we may need to relinquish certain valuable intellectual property or other rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. Even if we obtain additional funding, there can be no assurance that it will be available on terms acceptable to us or our stockholders.

Our common stock price may be highly volatile.

Since the completion of the merger with Seneca on April 27, 2021, the price of our common stock has been subject to significant fluctuation. Market prices for securities of biotechnology and other life sciences companies historically have been particularly volatile and may be subject to large daily price swings. Some of the factors that may cause the market price of our shares to fluctuate include, but are not limited to:

- failure of our product candidates to show safety and/or efficacy in our clinical trials;
- our ability to obtain timely regulatory approvals for our product candidates, and delays or failures to obtain such approvals;
- the results of our clinical trials, including our decision to pause or terminate any such trials;
- failure of our product candidates, if approved, to achieve commercial success;
- the entry into, or termination of, or breach by partners of key agreements, including the Giiant License Agreement, and employment agreements with our named executive officers;
- the initiation of, material developments in, or conclusion of any litigation to enforce or defend any intellectual property rights or defend against the intellectual property rights of others;
- announcements of any financings;
- announcements by commercial partners or competitors of new commercial products, clinical progress or the lack of, significant contracts, commercial relationships or capital commitments;
- failure to elicit meaningful stock analyst coverage and downgrades of our stock by analysts; and
- the loss of key personnel.

Moreover, the stock markets in general have experienced substantial volatility in the biotechnology industry, particularly in the micro-cap and nano-cap companies, that has often been unrelated to the operating performance of individual companies or a certain industry segment. These broad market fluctuations may also adversely affect the trading price of our shares. In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our profitability and reputation.

Our common stock could be delisted from the Nasdaq Stock Market if we are unable to maintain compliance with the Nasdaq Stock Market's continued listing standards.

Our common stock is listed on The Nasdaq Stock Market LLC ("Nasdaq"). There are a number of continued listing requirements that we must satisfy in order to maintain our listing on Nasdaq, including the requirement to maintain a minimum bid price of at least $1.00 (the "Bid Price Rule"). Although we are in compliance with the Bid Price Rule as of the date of this Annual Report on Form 10-K, we have been unable to comply with this rule in the past. For example, in October of 2023, we were notified that we were no longer in compliance with the Bid Price Rule and had 180 days to cure such deficiency. On April 5, 2024, we effected a 1-for-15 reverse stock split and we were notified by the Nasdaq that as of April 19, 2024, we were back in compliance with the Bid Price Rule. On April 30, 2025, we were notified again that we were no longer in compliance with the Bid Price Rule and had 180 calendar days to cure such deficiency. On August 5, 2025, the bid price of our common stock did close above $1.00 for 10 consecutive trading days, however, we were notified on August 6, 2025 that Nasdaq was exercising its discretion to continue monitoring our stock price beyond this ten-day period pursuant to Nasdaq Listing Rule 5810(c)(3)(H). As of October 15, 2025, the bid price of our common stock again closed above $1.00 for 10 consecutive days and we received a minimum bid price compliance letter from Nasdaq confirming that we regained compliance with Listing Rule 5550(a)(2), and that the matter is now closed.

We can provide no assurances that we will continue to comply with the Bid Price Rule or the other continued listing requirements of Nasdaq. The delisting of our common stock by Nasdaq could adversely affect the liquidity of our common stock, our ability to raise capital, create increased volatility in our common stock, and result in a loss of current or future coverage by analysts and/or diminish the interest of institutional investors to invest in our common stock. Delisting could also result in a loss of confidence of our collaborators, vendors and employees, which could harm our business and future prospects. If our common stock is delisted by Nasdaq, our common stock may be eligible to trade on the OTC Bulletin Board, OTCQB, OTCQX, or another over-the-counter market. Any such alternative would likely result in it being more difficult for us to raise additional capital through the public or private sale of equity securities and for investors to dispose of or obtain accurate quotations as to the market value of our common stock. Moreover, if our common stock is delisted, it may come within the definition of "penny stock" under the Securities Exchange Act of 1934, as amended, which imposes additional sales practice requirements on broker-dealers who sell securities to persons other than established customers and accredited investors. These requirements may reduce the trading activity in the secondary markets for our common stock and may impact the ability or willingness of broker-dealers to sell our securities which could limit the ability of stockholders to sell their securities in the public market and limit our ability to attract and retain qualified employees or raise additional capital in the future.

We take advantage of reduced disclosure and governance requirements applicable to smaller reporting companies, which could result in our common stock being less attractive to investors.

As of the last business day of our most recently completed second fiscal quarter, our public float was less than $250 million and therefore, we qualify as a smaller reporting company under SEC rules. As a smaller reporting company, we can take advantage of reduced disclosure requirements, such as simplified executive compensation disclosures and reduced financial statement disclosure requirements in our SEC filings. Such reduced disclosures in our SEC filings may make it harder for investors to analyze our results of operations and financial prospects. We cannot predict if investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of the reporting exemptions applicable to a smaller reporting company until we are no longer a smaller reporting company, which status would end once we have a public float greater than $250 million. In that event, we could still be a smaller reporting company if our annual revenues are below $100 million and we have a public float of less than $700 million.

We do not anticipate paying any dividends in the foreseeable future.

We do not anticipate paying any dividends in the foreseeable future. We currently plan to retain our future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, of our shares will likely be the sole source of gain, if any, for our stockholders for the foreseeable future.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock is and will be influenced by reports that equity research analysts publish about us and our business. Equity research analysts may elect not to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. In the event we do have equity research analyst coverage, we will not have any control over the analysts, or the content and opinions included in their reports. The price of our common stock could decline if one or more equity research analysts downgrades our stock or issues other unfavorable commentary or research. If one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our common stock could decrease, which in turn could cause our stock price or trading volume to decline.

Future sales of substantial amounts of our common stock, or the possibility that such sales could occur, could adversely affect the market price of our common stock.

Future sales in the public market of shares of our common stock, including shares issued upon exercise of our outstanding stock options or warrants, or the perception by the market that these sales could occur, could lower the market price of our common stock or make it difficult for us to raise additional capital.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us more difficult and may prevent attempts by our stockholders to replace or remove our management.

Provisions in our certificate of incorporation, as amended (“Certificate of Incorporation”), and bylaws, as amended (“Bylaws”) may delay or prevent an acquisition or a change in management. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits stockholders owning in excess of 15% of our outstanding voting stock from merging or combining with us. Although we believe these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirors to negotiate with our Board of Directors ("Board" or "Board of Directors"), they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove management by making it more difficult for stockholders to replace members of the Board, which is responsible for appointing the members of management.

If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of Nasdaq. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Annual Report on Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act. This has required that we incur substantial professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. We may experience difficulty in meeting these reporting requirements in a timely manner.

Our management identified a material weakness in our internal control over financial reporting. If we do not remediate this material weakness, or if we identify further material weaknesses in our internal controls, our failure to establish and maintain effective internal financial and accounting controls and procedures could result in material misstatements in our consolidated financial statements and a failure to meet our reporting and financial obligations.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate consolidated financial statements. If that were to happen, the market price of our common stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities.

Our Board has broad discretion to issue additional securities, which might dilute the net tangible book value per share of our common stock for existing stockholders.

We are entitled under our Certificate of Incorporation to issue up to 300,000,000 shares of common stock and 7,000,000 "blank check" shares of preferred stock. Shares of our blank check preferred stock provide our Board with broad authority to determine voting, dividend, conversion, and other rights of such preferred stock. As of December 31, 2025, we had outstanding, common stock or securities convertible into common stock, totaling 248,491,985 shares. As a result, we are authorized to issue up to an additional 51,508,015 shares of common stock or common stock equivalents under our Certificate of Incorporation. Additionally, pursuant to the initial issuance of (i) 1,000,000 shares of Series A 4.5% Convertible Preferred Stock, of which 200,000 shares are outstanding and (ii) 1,460 shares of Series B Convertible Preferred Stock, of which no shares are outstanding, we are authorized to issue up to an additional 6,800,000 shares of preferred stock. We expect that significant additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our existing stockholders will likely experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner that we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors will likely be materially diluted by the initial and subsequent sales. Additionally, new investors may gain rights superior to existing stockholders, depending on the terms of such transactions and types of securities. Pursuant to our equity incentive plans and employee stock purchase plan, management is authorized to grant stock options, restricted stock units and other equity-based awards to employees, directors and consultants, and to sell common stock to employees, respectively. Any increase in the number of shares outstanding as a result of the exercise of outstanding options, the vesting or settlement of outstanding stock awards, or the purchase of shares pursuant to the employee stock purchase plan will cause stockholders to experience additional dilution, which could cause our stock price to fall.

General Risk Factors

Our business could be adversely affected by the effects of health pandemics or epidemics, such as the COVID-19 pandemic, which could cause significant disruptions in our operations and those of our current or future CMOs, CROs, and other third parties upon whom we rely.

Health pandemics or epidemics, such as the COVID-19 pandemic, have in the past and could again in the future result in quarantines, stay-at-home orders, remote work policies, or other similar events that may disrupt businesses, delay our research and development programs and timelines, negatively impact productivity and increase risks associated with cybersecurity, the future magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations. More specifically, these types of events may negatively impact personnel at third-party manufacturing facilities or the availability or cost of materials, which could disrupt our supply chain. Moreover, our trials may be negatively affected. Clinical site initiation and patient enrollment may be delayed due to prioritization of hospital resources. Some patients may not be able or willing to comply with trial protocols if quarantines impede patient movement or interrupt healthcare services. Our ability to recruit and retain patients, principal investigators, and site staff (who as healthcare providers may have heightened exposure) may be hindered, which would adversely affect our trial operations. Disruptions or restrictions on our ability to travel to monitor data from our trials, or to conduct trials, or the ability of patients enrolled in our trials or staff at trial sites to travel, as well as temporary closures of our trial partners and CMOs' facilities, would negatively impact our trial activities. In addition, we rely on independent clinical investigators, CROs, and other third-party service providers to assist us in managing, monitoring, and otherwise carrying out certain of our preclinical studies and clinical trials, including the collection of data from our trials, and the effects of health pandemics or epidemics, such as the COVID-19 pandemic, may affect their ability to devote sufficient time and resources to our programs or to travel to sites to perform work for us. Similarly, our trials could be delayed and/or disrupted. As a result, the expected timeline for data readouts, including incompleteness in data collection and analysis and other related activities, and certain regulatory filings may be negatively impacted, which would adversely affect our ability to obtain regulatory approval for and to commercialize our product candidates, increase our operating expenses, and adversely affect our business, financial condition, results of operations, and prospects. In addition, impact on the operations of the FDA or comparable foreign regulatory authorities could negatively affect our planned trials and approval processes. Finally, economic conditions and business activity may be negatively impacted and may not recover as quickly as anticipated.

Global economic conditions may have an adverse effect on our business.

Financial instability or a general decline in economic conditions in the U.S. and other countries, caused by political instability, conflict, and economic challenges resulting from general health crises, has led to market disruptions, including significant volatility in commodity prices, credit and capital market instability, and supply chain interruptions. Such volatility, instability, and interruptions have contributed to record inflation globally and could adversely affect our operations. Increased inflation may result in higher operating costs (including labor costs), reduced liquidity, and limitations on our ability to access credit or raise capital on acceptable terms, if at all. Existing free trade laws and regulations, such as the United States-Mexico-Canada Agreement, provide certain beneficial duties and tariffs for qualifying imports and exports, subject to compliance with applicable classification and other requirements. However, changes in trade laws or policies, particularly increased trade restrictions, tariffs, or taxes on imports from countries where we manufacture products, such as Canada, China, and Mexico, could have a material adverse effect on our business and financial results. Since February of 2025, the U.S. government has enacted, and continues to enact, a series of new tariffs, including a tariff on all imports and additional "reciprocal" tariffs targeting imports from specified countries. These tariffs and other changes in U.S. trade policy have triggered, and could continue to trigger, retaliatory actions by affected countries, including retaliatory measures on U.S. goods and other protectionist measures that could limit our ability to offer our products and services outside of the U.S. The tariff policy environment has been and can be expected to continue to be dynamic. The ultimate impact of these newly enacted and potential future tariffs or other restrictions on international trade will depend on various factors, including the ultimate levels of such tariffs, how long such tariffs remain in place, and how other countries respond to the U.S. tariffs. Consequently, we cannot assure that any strategies we implement to mitigate the effects of such tariffs or trade actions will be successful. In addition, the U.S. Federal Reserve has raised, and may continue to raise, interest rates in response to concerns about inflation. Inflation, combined with reduced government spending and volatility in financial markets, may further increase economic uncertainty and heighten associated risks. Economic conditions and uncertainty regarding the broader macroeconomic environment are beyond our control and may make obtaining necessary debt or equity financing more difficult, costly, and dilutive. While we believe we have adequate capital resources to meet current working capital and capital expenditure requirements, an economic downturn or a significant increase in expenses could necessitate additional financing under less favorable conditions, including unattractive interest rates or excessively dilutive terms for existing stockholders. Failure to secure necessary financing in a timely manner and on favorable terms could materially and adversely affect our stock price and force us to delay or abandon clinical development plans.

Inadequate funding for the FDA, the SEC and other government agencies, including from government shutdowns, or other disruptions to these agencies' operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, the ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which could adversely affect our business. If there are significant employee reductions at the FDA or a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future reductions in force and government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. For example, over the last several years the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities. In addition, federal employees recently have been subject to termination in connection with cost reduction efforts by the federal government. If a prolonged government shutdown or significant reduction in force of federal employees occurs, including those working for the FDA, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Further, future government shutdowns and cost-cutting efforts could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

If our information systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse consequences.

In the ordinary course of our business, we may process, as defined above, proprietary, confidential, and sensitive data, including personal data (such as health-related patient data), intellectual property, and trade secrets (collectively, sensitive information). We may rely upon third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, third-party providers of cloud-based infrastructure, employee email, CROs, and other functions. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. We may share or receive sensitive information with or from third parties.

The risk of a security breach or disruption, particularly through cyber-attacks, cyber-intrusion, malicious internet-based activity, and online and offline fraud, are prevalent and have generally increased as the number, intensity, and sophistication of attempted attacks and intrusions from around the world have increased. These threats are becoming increasingly difficult to detect and come from a variety of sources, including traditional computer hackers, threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors. Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including cyber-attacks that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our products.

We and the third parties upon which we rely may be subject to a variety of evolving threats, including but not limited to social engineering attacks (including through phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, natural disasters, terrorism, war, and telecommunication and electrical failures. Ransomware attacks, including by organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and can lead to significant interruptions in our operations, loss of data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Similarly, supply-chain attacks have increased in frequency and severity.

Furthermore, our remote workforce poses increased risks to our information technology systems and data, as most of our employees work from home, utilizing network connections outside our premises.

Any of the previously identified or similar threats could cause a security breach or disruption. While we have not experienced any such security breach or other disruption to date, if such an event were to occur, it could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information and cause interruptions in our operations, including material disruptions of our development programs and business operations.

We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security breaches and disruptions. While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We may be unable in the future to detect vulnerabilities in our information technology systems because such threats and techniques change frequently, are often sophisticated in nature, and may not be detected until after a security breach or disruption has occurred. Despite our efforts to identify and remediate vulnerabilities, if any, in our information technology systems, our efforts may not be successful. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities.

Applicable data privacy and security obligations may require us to notify relevant parties of certain security breaches and disruptions. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a security

breach or other disruption, or are perceived to have experienced such events, we may experience adverse consequences, including: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. In particular, since we sponsor clinical trials, any breach or disruption that compromises patient data and identities could generate significant reputational damage, which may affect trust in us and our ability to recruit for future clinical trials. Additionally, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. Furthermore, we cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

Our business and operations would suffer in the event of system failures, cyber-attacks or a deficiency in our cybersecurity.

Despite the implementation of security measures, our internal computer systems, and those of our current and future CROs and other contractors and consultants, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Although we have not suffered any material incidents to date, the risk of a security breach or disruption, particularly through cyber-attacks or cyber-intrusion, including by computer hackers, foreign governments, and cyber-terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. While we have not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. In addition, since we sponsor clinical trials, any breach that compromises patient data and identities causing a breach of privacy could generate significant reputational damage and legal liabilities and costs to recover and repair, including affecting trust in us to recruit for future clinical trials. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our products and product candidates could be delayed.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

In the ordinary course of our business, we may process proprietary, confidential, and sensitive data, including personal data (such as health-related patient data), intellectual property, and trade secrets (collectively, "sensitive information"). We rely upon third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, third-party providers of cloud-based infrastructure, employee email, CROs, and other functions. The secure maintenance of this sensitive information and our information technology systems is important to our operations. To this end, we have processes designed to assess, identify, and manage risks from potential unauthorized occurrences on or through our information technology systems that may result in adverse effects on the confidentiality, integrity, and availability of these systems and the data residing therein. These processes are managed and monitored by our third-party information technology consultants and include mechanisms, controls, technologies, systems, and other processes designed to prevent or mitigate data loss, theft, misuse, or other security incidents or vulnerabilities affecting the data and maintain a stable information technology environment.

Risk Management and Strategy

We are planning to establish an appropriate confidentiality framework and document management system in order to safeguard sensitive information in addition to the safeguards provided by our third-party service providers. Such confidentiality framework may include the use of third-party information technology experts to manage and oversee our sensitive information and to work directly with our management in overseeing cybersecurity risks and appropriate responses thereto. In addition, we plan to consult with outside advisors and experts, when appropriate, to assist with assessing and identifying cybersecurity risks, including to anticipate future threats and trends, and their impact on our risk environment.

In the last fiscal year, we have not identified risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected us, but we face certain ongoing cybersecurity risks threats that, if realized, are reasonably likely to materially affect us. Additional information on cybersecurity risks faced by us are discussed in Part I, Item 1A, "Risk Factors," under the headings "*If our information systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse consequences*" and "*Our business and operations would suffer in the event of system failures, cyber-attacks or a deficiency in our cybersecurity.*"

Governance

Our Board, as a whole and at the committee level, has oversight for the most significant risks facing us and for our processes to identify, prioritize, assess, manage, and mitigate those risks. The audit committee of our Board (the ("Audit Committee"), which is comprised solely of independent directors, has been designated by our Board to oversee cybersecurity risks. The Audit Committee receives updates, as needed, on cybersecurity and information technology matters and related risk exposures.

Item 2. Properties.

None.

Item 3. Legal Proceedings.

From time to time, we may be involved in various lawsuits, legal proceedings or claims that arise in the ordinary course of our business. We do not believe there are any claims or actions pending against the Company through December 31, 2025, which will have, individually or in aggregate, a material adverse effect on our business, liquidity, financial position, or results of operations. Litigation, legal proceedings or claims, however, are subject to inherent uncertainties, and an adverse result in such matters may arise from time to time that may harm our business because of defense and settlement costs, diversion of management resources, and other factors.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock trades on the Nasdaq Capital Market under the symbol "PALI." On March 18, 2026, the last reported sale price our common stock on the Nasdaq Capital Market was $1.97 per share.

Holders

As of March 18, 2026, there were 134 holders of record of our common stock, which does not include stockholders who hold shares in street name or stockholders whose shares may be held in trust by other entities.

Dividend Policy

We have never declared or paid cash dividends on our common stock. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any dividends on our common stock in the foreseeable future. Any future determination to declare dividends will be made at the discretion of our Board of Directors and will depend on, among other factors, our financial condition, operating results, capital requirements, contractual restrictions, general business conditions and other factors that our Board of Directors may deem relevant.

Recent Sales of Unregistered Equity Securities

On December 17, 2025, we entered into a Research Program Funding Agreement (the "CCF Funding Agreement") with the Crohn's & Colitis Foundation (the "CCF"), in which the CCF agreed to provide up to a $0.5 million investment in return for shares of our common stock.

The funding is payable in three tranches ("CCF Milestone Payment(s)") subject to the achievement of three specified milestones. For each CCF Milestone Payment received, we must issue shares of our common stock equal to the CCF Milestone Payment amount divided by 80% of the closing price of our common stock on the date of the respective CCF Milestone Payment cash receipt date. As of December 31, 2025, we have not issued any shares of our common stock under the CCF Funding Agreement

The sales of the securities described above were exempt from registration under the Securities Act under Section 4(a)(2) of the Securities Act as transactions by an issuer not involving a public offering. No underwriters were involved in the sales.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. [Reserved.]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

*Statements in this Annual Report on Form 10-K that are not strictly historical are "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These statements relate to future events or to our future operating or financial performance and involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statem*ents. *You can identify these forward-looking statements because they involve our expectations, intentions, beliefs, plans, projections, anticipations, or other characterizations of future events or circumstances. These forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that may cause actual results to differ materially from those in the forward-looking statements as a result of any number of factors. Some of these factors are more fully discussed in the section of this Annual Report on Form 10-K entitled "Risk Factors" and elsewhere herein. We do not undertake to update any of these forward-looking statements or announce the results of any revisions to these forward-looking statements except as required by law.*

We recommend investors read this entire Annual Report on Form 10-K, including the "Risk Factors" section, the consolidated financial statements, and related notes thereto. As used in this Annual Report on Form 10-K, unless the context indicates or otherwise requires, "Palisade," "Palisade Bio," the "Company," "we," "us," and "our" or similar designations in this report refer to Palisade Bio, Inc., a Delaware Corporation, and its subsidiaries. Any reference to "common shares" or "common stock," refers to our $0.01 par value common stock. Any reference to "Leading Biosciences, Inc." or "LBS" refers to our operations prior to the completion of our merger with Seneca Biopharma, Inc. ("Seneca") on April 27, 2021 (the "Seneca Merger"). Any technology that we currently own or may acquire the rights to in the future is referred to by us as either a "product candidate" or "product candidates." Additionally, any reference herein that refers to preclinical studies also refers to nonclinical studies.

OVERVIEW

We are a clinical-stage biopharmaceutical company developing next-generation, once-daily, oral phosphodiesterase-4 ("PDE4") inhibitor prodrugs designed for targeted delivery to the terminal ileum and colon. Our lead clinical product candidate, PALI-2108, is being developed as a treatment for patients living with inflammatory bowel disease ("IBD"), including ulcerative colitis ("UC") and Crohn's disease ("CD").

During 2025, we announced positive results from our Phase 1 human clinical trial of PALI-2108 for the treatment of UC conducted in Canada. The Phase 1 clinical study of PALI-2108 was a single-center, randomized, double-blinded, placebo-controlled clinical study focused on safety, tolerability, and pharmacokinetics ("PK") in both healthy volunteers and UC patients. The clinical study included an open-label UC patient cohort with multiple dosing arms in which we evaluated the pharmacodynamics ("PD") of PALI-2108. On October 16, 2025, we dosed our first patients in an exploratory Phase 1b cohort in Fibrostenotic Crohn's disease ("FSCD") while we complete longer-term chronic safety and toxicology studies. The exploratory Phase 1b cohort in FSCD is expected to be followed by the initiation of Phase 2 clinical programs to assess PALI-2108's efficacy, safety, and tolerability in patients with moderate to severe UC, as well as those with CD.

In addition to conducting clinical studies in Canada, we anticipate data from the exploratory Phase 1b cohort in FSCD together with results from the Phase 1/1b UC program will support Investigational New Drug Application ("IND") submissions to the United States Food and Drug Administration ("FDA") for a Phase 2 UC study in the second quarter of 2026 and a Phase 2 CD study in the second half of 2026.

Crohn's and Colitis Foundation Research Funding Agreement

On December 17, 2025, we entered into a Research Program Funding Agreement (the "CCF Funding Agreement") with the Crohn's & Colitis Foundation (the "CCF"), in which the CCF agreed to provide up to a $0.5 million investment to support our Phase 1b research program related to PALI-2108 in exchange for shares of our common stock.

October 2025 Offering

On October 2, 2025, we closed on an underwritten public offering to issue and sell 197,154,844 shares of common stock and common stock equivalents for net proceeds, including the full exercise of the underwriter's over-allotment option, of approximately $127.6 million, consisting of gross cash proceeds of $138.0 million less underwriting discounts and commissions and other cash equity issuance costs of approximately $10.4 million (the "October 2025 Offering").

July 2025 Warrant Inducement Transaction

On July 23, 2025, we entered into a warrant inducement agreement with an existing holder of certain of our common stock warrants to exercise their existing common stock warrants to purchase an aggregate of 4,318,905 shares of our common stock. The transaction closed on July 25, 2025 for net cash proceeds of approximately $3.4 million consisting of gross cash proceeds of $3.9 million, less cash equity issuance costs of approximately $0.5 million.

Financial Results

Our operating loss for the year ended December 31, 2025 was approximately $18.1 million, which consisted of research and development expenses and general and administrative expenses of approximately $10.2 million and $7.9 million, respectively. Net cash used in operating activities was approximately $10.8 million for the year ended December 31, 2025, which includes a $16.8 million net loss adjusted for $1.6 million of net cash inflows related to changes in operating assets and liabilities and certain non-cash items impacting the net loss. Net cash provided by financing activities was approximately $134.4 million for the year ended December 31, 2025. As of December 31, 2025, we have $133.4 million in cash, cash equivalents and restricted cash.

FINANCIAL OVERVIEW

Research and Development Expenses

Our research and development expenses include:

- salaries and employee-related costs, including stock-based compensation;
- laboratory and vendor expenses related to the execution of preclinical and clinical trials;
- expenses under agreements with third-party contract research organizations ("CROs"), investigative clinical trial sites that conduct research and development activities on our behalf, and consultants;
- costs related to develop and manufacture preclinical study and clinical trial material; and
- regulatory expenses.

Through the majority of 2024, the nature of our research and development expenses incurred related primarily to the preclinical activities associated with our joint development of PALI-2108 with our collaboration partner, Giiant Pharma Inc. ("Giiant"). With the approval to commence the Phase 1 clinical trial of PALI-2108, which we received from Health Canada on October 9, 2024, pursuant to terms of the research and collaboration agreement that we have with Giiant ("Giiant License Agreement"), we have assumed all development, manufacturing, regulatory and commercialization activities and costs of PALI-2108. Therefore, our clinical research and development costs directly attributable to the clinical trials of PALI-2108 were higher in 2025 as compared to 2024, offset by a decrease in joint development costs associated with the Giiant License Agreement. We expect our clinical research and development costs will continue to increase in 2026 as we advance PALI-2108 through clinical studies in UC and CD.

Our direct research and development expenses are tracked by product candidate and consist primarily of external costs, such as fees paid under third-party license agreements and to outside consultants, CROs, clinical sites, contract manufacturing organizations (“CMOs”) and research laboratories in connection with our preclinical development, process development, manufacturing, clinical development, and regulatory activities. We do not allocate employee costs and costs associated with our discovery efforts, laboratory supplies and facilities, including other indirect costs, to specific product candidates because these costs are deployed across multiple programs and, as such, are not separately classified. As needed, we manage third parties that are engaged to conduct our (i) research activities, (ii)

preclinical, clinical and translational science development activities, (iii) drug manufacturing activities, and (iv) process development. When we perform any research and development or manufacturing activities under a co-development agreement, we record the expense reimbursement from the co-development partner as a reduction to research and development expense once the reimbursement amount is approved for payment by the co-development partner. Pursuant to agreements where we perform research and development activities under a joint development plan, such as our research and collaboration with Giiant, qualifying development costs are expensed as research and development costs as incurred. We recognize expense payments from Giiant, if any, as a reduction to research and development expense once the expense payments are realized or realizable, which is when we receive the cash or we have an undisputed claim to the cash that is probable of collection.

General and Administrative Expenses

Our general and administrative expenses consist primarily of (i) salary and employee-related costs and benefits, including stock-based compensation, (ii) professional fees for legal, intellectual property, investor and public relations, accounting and audit services, insurance costs, director and committee fees, and (iii) general corporate expenses.

Reverse Stock Split

On April 5, 2024, we effected a 1-for-15 reverse stock split of our issued and outstanding common stock (the "Reverse Stock Split"). As a result of the Reverse Stock Split, each our stockholders received one share of our common stock for every 15 shares such stockholder held immediately prior to the effective time of the Reverse Stock Split. Unless otherwise noted, all common stock shares, common stock per share data and shares of common stock underlying convertible preferred stock, stock-based awards and common stock warrants included in this Annual Report on Form 10-K, including the exercise or conversion price of such equity instruments, as applicable, have been retrospectively adjusted to reflect the Reverse Stock Split.

Results of Operations

The following table summarizes our results of operations for the year ended December 31, 2025 and 2024 (in thousands):

	Year Ended December 31,		Change	
	2025	2024	$	%
Operating expenses:				
Research and development	$ 10,192	$ 9,063	$ 1,129	12%
General and administrative	7,864	5,796	2,068	36%
Total operating expenses	18,056	14,859	3,197	22%
Loss from operations	(18,056)	(14,859)	(3,197)	22%
Other (expense) income:				
Interest expense	(10)	(12)	2	(17)%
Other income, net	1,285	433	852	197%
Total other income, net	1,275	421	854	203%
Net loss	$ (16,781)	$ (14,438)	$ (2,343)	16%

Research and Development Expenses

Our research and development expenses increased by approximately $1.1 million, or 12%, from approximately $9.1 million for the year ended December 31, 2024 to approximately $10.2 million for the year ended December 31, 2025. The increase is primarily attributable to (i) an approximately $2.8 million increase in research and development employee-related expenses, (ii) an approximately $2.5 million net increase in clinical trial-related expenses associated with the Phase 1 clinical trial of PALI-2108, (iii) an approximately $0.9 million increase in chemistry, manufacturing and controls ("CMC") expenses, and (iv) and an approximately $0.4 million net non-cash loss associated with an increase in the fair value of the contingent consideration obligation pursuant to the Giiant License Agreement. These increases were partially offset by an approximately $5.4 million decrease in expenses that were directly related to the preclinical joint development of PALI-2108.

Research and development employee-related expenses increased approximately $2.8 million for the year ended December 31, 2025, compared to the year ended December 31, 2024, primarily due to an approximately $1.9 million increase in non-cash share-based compensation expense and an approximately $0.9 million increase in research and development salaries and benefits expense as a result of a 133% increase in research and development headcount necessary to support our PALI-2108 development strategy subsequent to the October 2025 Offering, and to a lesser extent, an increase in employee annual bonuses.

We recognized clinical trial-related expenses of approximately $4.0 million for the year ended December 31, 2025, compared to clinical trial-related expenses of $1.5 million for the year ended December 31, 2024, an increase of approximately $2.5 million due to the commencement of our Phase 1 clinical trial of PALI-2108 in November of 2024. CMC expenses increased from approximately $1.0 million for the year ended December 31, 2024 to approximately $1.9 million for the year ended December 31, 2025, primarily due to increased activity related to our upcoming clinical trials.

Preclinical joint development expenses were approximately $4.3 million for the year ended December 31, 2024. We recognized no preclinical joint development costs for the year ended December 31, 2025. In addition, during the year ended December 31, 2025, we recognized a reduction in joint development costs of $1.1 million that was related to funds received by us from Giiant pursuant to the joint development plan, resulting in a net decrease in preclinical joint development expenses of approximately $5.4 million for the year ended December 31, 2025, compared to the year ended December 31, 2024.

We recognized an approximate $0.4 million non-cash loss on the fair value remeasurement of the contingent consideration obligation for the year ended December 31, 2025, compared to an approximate $0.1 million non-cash gain on the fair value remeasurement of the contingent consideration obligation for the year ended December 31, 2024, resulting in a net non-cash year-over-year loss of approximately $0.4 million. On October 16, 2025, the first of the milestones pursuant to the Giiant License Agreement was achieved with the dosing of the first patient in the Company's Phase 1b clinical trial of PALI-2108 in a FSCD cohort. Accordingly, the Company settled this a milestone payment to Giiant in cash in the amount of approximately $0.2 million.

General and Administrative Expenses

Our general and administrative expenses increased by approximately $2.1 million, or 36%, from approximately $5.8 million for the year ended December 31, 2024 to approximately $7.9 million for the year ended December 31, 2025, primarily as a result of (i) an approximately $1.7 million increase in general and administrative employee-related expenses due to an approximately $1.4 million increase in non-cash share-based compensation expense and an approximately $0.3 million increase in salaries and benefits and annual bonuses, (ii) an approximately $0.4 million increase in professional fees and legal expenses, (iii) an approximately $0.1 million increase in shareholder services due to the special meetings of stockholders held in 2025, and (iv) an approximately $0.1 million increase in general operating expenses. These increases were partially offset by an approximately $0.2 million decrease in consultant and contract labor expenses.

Other income (expense)

Other income, net, increased by approximately $0.9 million, or 197%, from approximately $0.4 million for the year ended December 31, 2024 to approximately $1.3 million for the year ended December 31, 2025, primarily as a result of an approximately $0.9 million increase in dividend income, due to the increased investment of excess cash in money market accounts after the October 2025 Offering, and other non-cash losses of less than $0.1 million associated primarily with the write-off of certain other receivable balances for the year ended December 31, 2024 that did not repeat in 2025, partially offset by a non-cash loss of approximately $0.1 million recognized for the year ended December 31, 2025 that related to the fair value of the milestone liabilities recognized upon our entering into the CCF Funding Agreement (Note 5, *Stockholders' Equity* in Part II Item 8 of this Annual Report on Form 10-K for further details).

Liquidity and Capital Resources

We expect to incur substantial losses for the foreseeable future. Since our inception, we have financed our operations through the sales of our securities, issuance of debt, the exercise of common stock warrants, and to a lesser degree, grants and research contracts as well as the licensing of our intellectual property to third parties.

Management believes the October 2025 Offering for net proceeds of $127.6 million will provide sufficient capital to fund our operations through major clinical development milestones including a Phase 2 primary efficacy readout of PALI-2108 for UC that is expected in the second half of 2027 and a Phase 2 primary efficacy readout of PALI-2108 for CD that is expected in 2028.

Sources of Liquidity

Future capital requirements will depend upon many factors, including the timing and extent of spending on research and development and market acceptance of our products, if approved for commercial sale. We will require additional funding to conduct future clinical activities. We may seek additional funding through public and private financings, debt financings, collaboration agreements, strategic alliances and licensing agreements. Although we have been successful in raising capital in the past, there is no assurance of success in obtaining such additional financing on terms acceptable to us, if at all, and there is no assurance that we will be able to enter into collaborations or other arrangements. If we are unable to obtain funding, it could force delays, reduce or eliminate research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect our future business prospects, and the ability to continue operations.

Pursuant to the October 2025 Offering, we issued and sold (a) 113,240,564 shares of our common stock, par value $0.01 per share, at a public offering price of $0.70 per share, and (b) 83,914,280 pre-funded warrants to purchase one share of the our common stock, par value $0.01 per share, at a public offering price of $0.6999 per share. Net proceeds from the offering, including the full exercise of the underwriter's over-allotment option, were approximately $127.6 million, consisting of gross cash proceeds of $138.0 million less underwriting discounts and commissions and other cash equity issuance costs of approximately $10.4 million. We intend to use the net proceeds from the offering for working capital and general corporate purposes, including the development of PALI-2108 for the treatment of UC and CD.

Refer to Note 5, *Stockholders' Equity* in Part II Item 8 of this Annual Report on Form 10-K for further details of our recent equity transactions.

Warrant Exercises

During the years ended December 31, 2025 and December 31, 2024, total gross cash proceeds from the exercise of outstanding common stock warrants was approximately $7.6 million and $2.5 million, respectively, primarily as a result of the transactions described below.

On July 23, 2025, we entered into an agreement with an accredited and institutional holder (the “July 2025 Warrant Holder”) of certain of our existing common stock warrants (the “July 2025 Existing Warrant(s)”) to exercise the July 2025 Existing Warrants to purchase up to an aggregate of 4,318,905 shares of our common stock (the "July 2025 Warrant Inducement Agreement"). Pursuant to the July 2025 Warrant Inducement Agreement, the exercise price of each July 2025 Existing Warrant exercised was reduced from $1.40 per share to $0.9047 per share. In consideration for the immediate exercise of the July 2025 Existing Warrants, the July 2025 Warrant Holder received new warrants (the “July 2025 Replacement Warrants”) to purchase shares of common stock in a private placement. Pursuant to the July 2025 Warrant Inducement Agreement, the July 2025 Warrant Holder received two July 2025 Replacement Warrants for each July 2025 Existing Warrant exercised (in its entirety, the "July 2025 Warrant Inducement Transaction"). The transaction closed on July 25, 2025 with the Company receiving net cash proceeds of approximately $3.4 million, which consisted of gross cash proceeds of $3.9 million from the exercise of the July 2025 Existing Warrants, less cash equity issuance costs of approximately $0.5 million. We intend to use the net proceeds from the July 2025 Warrant Inducement Transaction for working capital and general corporate purposes, including the development of PALI-2108 for the treatment of UC and CD.

Also during the year ended December 31, 2025, we received gross proceeds of approximately $3.7 million from the exercise of 3,224,209 common stock warrants that were issued to representatives of the sole underwriter in the October 2025 Offering.

On January 30, 2024, we entered into warrant inducement agreements (the “February 2024 Warrant Inducement Agreements”) with certain accredited and institutional holders (collectively, the “February 2024 Warrant Holders”) of certain of existing common stock warrants (the “February 2024 Existing Warrants”) to exercise the February 2024 Existing Warrants to purchase up to an aggregate of 228,162 shares of our common stock. Pursuant to the February 2024 Warrant Inducement Agreements, the exercise price of each February 2024 Existing Warrant was

reduced to $10.97 per share. In consideration for the immediate exercise of the February 2024 Existing Warrants, each of the February 2024 Warrant Holders received one replacement warrant for each February 2024 Existing Warrant exercised. The transaction closed on February 1, 2024 for net cash proceeds of approximately $2.2 million consisting of gross cash proceeds of approximately $2.5 million, less cash equity issuance costs of approximately $0.3 million.

Cash Flows

As of December 31, 2025, we had $133.4 million in cash, cash equivalents and restricted cash. The following table shows a summary of our cash flows for the years ended December 31, 2025 and 2024 (in thousands):

	Year Ended December 31,	
	2025	2024
Net cash used in operating activities	$ (10,847)	$ (12,193)
Net cash provided by financing activities	134,440	9,582

Net Cash Used in Operating Activities

Cash used in operations decreased by approximately $1.3 million for the year ended December 31, 2025 compared to the year ended December 31, 2024 primarily due to a decrease in net loss after adjusting for non-cash items impacting the net loss, primarily stock-based compensation and related charges, and favorable changes in operating assets and liabilities.

Cash used in operating activities was approximately $10.8 million for the year ended December 31, 2025, which reflects an approximately $16.8 million net loss adjusted for (i) approximately $1.6 million of net cash inflows related to changes in operating assets and liabilities, and (ii) certain non-cash items impacting the net loss, consisting primarily of (a) an approximately $4.0 million non-cash expense recognized for stock-based compensation and related charges, (b) an approximately $0.3 million non-cash expense recognized for the fair value remeasurement of certain financial instrument liabilities, primarily our contingent consideration obligation, partially offset by an approximately $0.2 million payment of our contingent consideration obligation, (c) an approximately $0.1 million non-cash expense recognized for the discount on the common shares to be issued pursuant to the CCF Funding Agreement, (d) an approximately $0.1 million non-cash expense related to the amortization of our operating lease right of use asset, and (e) an approximately $0.1 million non-cash expense related to the write-off of certain deferred equity issuance costs associated with our shelf registration statement that expired in April of 2025. The net cash inflow from operating assets and liabilities was primarily attributable to (i) a net cash inflow of approximately $0.5 million from prepaids and other current assets and other noncurrent assets, which was primarily attributable to the amortization of the current and non-current portions of our prepaid insurance policies, (ii) an approximately $0.6 million increase in accounts payable and accrued liabilities, primarily due to higher clinical trial-related expenses and translational science expenses as a result of increased clinical trial activity, partially offset by lower accrued joint development expenses associated with the Giiant License Agreement, and (iii) an approximately $0.6 million increase in accrued compensation and benefits due to an increase in the employee bonus accrual, which will be paid in 2026. The operating asset and liabilities inflows were partially offset by an approximately $0.1 million cash outflow related to payments of our operating lease.

Cash used in operating activities was approximately $12.2 million for the year ended December 31, 2024, which reflects an approximately $14.4 million net loss adjusted for (i) approximately $1.4 million of net cash inflows related to changes in operating assets and liabilities, and (ii) certain non-cash items impacting the net loss, consisting primarily of (a) an approximately $0.7 million non-cash expense recognized for stock-based compensation and related charges, (b) an approximately $0.1 million non-cash expense associated with the issuance of our common stock as payment for vendor services provided, and (c) an approximately $0.1 million non-cash expense related to the amortization of our operating lease right of use asset. The net cash inflow from operating assets and liabilities was primarily attributable to an approximately $0.1 million cash outflow related to payments of our operating lease that was more than offset by approximately $1.6 million cash inflow from (i) an approximately $0.8 million decrease in prepaids and other current assets and other noncurrent assets, which was primarily attributable to the amortization of the current and non-current portions of our prepaid insurance policies, and (ii) an approximately $0.8 million increase in accounts payable and accrued liabilities, which was primarily due to additional drug manufacturing accruals associated with the clinical trials of PALI-2108 and an increase in accrued joint

development expenses associated with the Giiant License Agreement. These increases in accounts payable and accrued liabilities were partially offset by a decrease in accrued severance payments and lower accrued fees to our board of directors ("Board") and Board committee fees.

Net Cash Provided by Financing Activities

For the year ended December 31, 2025, cash provided by financing activities of approximately $134.4 million was attributable to cash proceeds net of underwriting discounts and commissions and cash equity issuance costs of approximately $127.6 million from the October 2025 Offering and net cash proceeds of approximately $7.1 million from the exercise of common stock warrants, including those exercised in conjunction with the July 2025 Warrant Inducement Transaction, partially offset by payments made on our insurance financing arrangements of approximately $0.3 million.

For the year ended December 31, 2024, cash provided by financing activities of approximately $9.6 million was attributable to net cash proceeds of approximately $2.2 million from the exercise of common stock warrants in conjunction with our warrant inducement transaction in February 2024, net cash proceeds of approximately $3.5 million from our private placement financing completed in May of 2024, and cash proceeds net of underwriting discounts and commissions and cash equity issuance costs of approximately $4.4 million from our underwritten public offering of stock completed in December of 2024, partially offset by payments made on our insurance financing arrangements of approximately $0.4 million.

Contractual Obligations

Insurance Financing Arrangement

In June of 2025, we entered into an agreement to finance an insurance policy that renewed in May of 2025. The insurance financing arrangement is secured by the associated insurance policy and is payable over a 9-month period commencing with the first payment that was payable on June 30, 2025. As of December 31, 2025, the aggregate remaining balance under our insurance financing arrangement of approximately $0.1 million will be paid in the first quarter of 2026.

Other than the remaining insurance financing arrangement payments due in 2026, as of December 31, 2025 we have no other minimum debt payments required in 2026 or thereafter.

Future Liquidity Needs

We have incurred significant operating losses and negative cash flows from operations since our inception. To date, we have not been able to generate significant revenues nor achieve operating profitability. Based upon our cash and cash equivalents balance of $133.4 million as of December 31, 2025, we believe we have sufficient capital to fund our operations through major clinical development milestones including a Phase 2 primary efficacy readout of PALI-2108 for UC that is expected in the second half of 2027 and a Phase 2 primary efficacy readout of PALI-2108 for CD that is expected in 2028. Notwithstanding, should our anticipated level of operations significantly change, we may require additional financing sooner than anticipated. Further, beyond the readout expected in 2028, we will require additional financing to continue at our expected level of operations, including a Phase 3 clinical trial and possible commercialization of PALI-2108 for the treatment of UC and CD.

Critical Accounting Policies and Estimates

Our consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the U.S. (“U.S. GAAP”). The preparation of financial statements in conformity with U.S. GAAP requires us to make estimates, judgments, and assumptions that impact the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities as of the date of the balance sheet and the reported amounts of expenses during the reporting period. Our estimates are based on historical experience, known trends, events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. In making estimates and judgments, management employs critical accounting policies.

Our significant accounting policies used in the preparation of the consolidated financial statements are described in more detail in Note 2 in Part II, "Item 8. Financial Statement and Supplemental Data" of this Annual Report on Form 10-K. We believe that the following accounting policies are the most critical for fully understanding and evaluating our financial condition and results of operations:

Accrued research and development expenses

We expense research and development costs as incurred pursuant to Accounting Standards Codification ("ASC") 730, *Research and Development Costs*. We are required to make estimates of our accrued expenses resulting from our obligations under contracts or agreements with, as applicable, research and development collaboration partners, CROs, clinical sites, manufacturers, vendors, and consultants in connection with conducting research and development activities, including those related to our ongoing clinical operations. The financial terms of these contract arrangements are subject to negotiation, vary from contract to contract, and may result in uneven payment flows that do not match the periods over which services are provided or milestones are met under the associated research and development contract. Payments under some of these contracts depend on factors such as the successful enrollment of patients, site initiation and the completion of clinical milestones. We make estimates of our accrued research and development expenses as of each balance sheet date based on facts and circumstances known at that time. We accrue for research and development expenses for which the estimated services have been provided but we have not yet been invoiced as of the balance sheet date. There may be instances in which payments made to our service providers will temporarily exceed the level of services provided and result in a prepayment of the research and development expenses. If the actual timing of the performance of services or the level of effort varies from its estimate, we adjust the accrual or prepaid expense balance accordingly.

Our process around estimating accrued research and development expenses involves reviewing open contracts and purchase requisitions, communicating with our personnel, consultants, and research and development collaboration partners to identify services that have been performed on our behalf, and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost.

Expense payments made to Giiant pursuant to the terms of the Giiant License Agreement for qualifying development costs are expensed only as the associated research and development costs are incurred or other aspects of the drug development or related activities are achieved. In instances where the expense determined to be recognized exceeds the payments made to the Giiant, we recognize an accrual of joint development expenses. In addition, there may be instances in which payments made to Giiant will temporarily exceed the level of services provided, which results in a prepayment of the joint development expenses. We record expense payments from Giiant, if any, as a reduction to research and development expense once the expense payments are realized or realizable, which is when Company receives the cash or has an undisputed claim to the cash that is probable of collection, pursuant to the terms of the Giiant License Agreement and the principles of ASC 450, *Gain Contingencies*. The Company has determined that Giiant is not considered a customer under ASC 606.

Although we do not expect our estimates of research and development expenses to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting amounts that are too high or too low in any particular period.

Contingent Consideration Obligation

Pursuant to the Giiant License Agreement, we incurred a contingent consideration obligation consisting of milestone payments. Because the contingent consideration associated with the milestone payments may be settled in shares of our common stock solely at the election of the Company, we have determined it should be accounted for under ASC 480, *Distinguishing Liabilities from Equity* and accordingly we have recognized it as a liability measured at its estimated fair value. As of September 1, 2023, the date the contingent consideration obligation was incurred, the initial fair value of the liability was determined to be approximately $0.2 million.

At the end of each reporting period, we remeasure the contingent consideration obligation to its estimated fair value and any resulting change is recognized in research and development expenses in the consolidated statements of operations. The fair value of the contingent consideration obligation is determined using a probability-based model that estimates the likelihood of success in achieving each of the defined milestones, which is then discounted to present value using our incremental borrowing rate. The fair value measurement is based on significant inputs not

observable in the market and thus represents a Level 3 measurement as defined in ASC 820, *Fair Value Measurements and Disclosures*. The significant assumptions used in the calculation of the fair value as of December 31, 2025 included a discount rate of 15.26% and management's updated projections of the likelihood of success in achieving the one remaining defined milestone based on empirical, published industry data.

As of December 31, 2025 and December 31, 2024, the entire amount of contingent consideration obligation of approximately $0.3 million and $0.2 million, respectively, was classified as a noncurrent liability in the consolidated balance sheets.

The change in the fair value of the contingent consideration obligation for the year ended December 31, 2025 was a loss of approximately $0.4 million, primarily due to an increase in the liability concurrent with the expected dosing our first patients in an exploratory Phase 1b cohort in FSCD, which with an amendment in the trial protocol we determined met the milestone definition pursuant to the Giiant License Agreement. The milestone was achieved on October 16, 2025 and we settled this a milestone payment to Giiant in cash in the amount of approximately $0.2 million in the fourth quarter of 2025.

The change in the fair value of the contingent consideration obligation for the year ended December 31, 2024 was a gain of approximately $0.1 million and was primarily due to the reduction in the milestone payments that would be due to Giiant upon the achievement of certain development milestones pursuant to an amendment to the Giiant License Agreement, partially offset by an increase in management's projected likelihood of success in achieving each of the defined milestones as a result of our commencement of a Phase 1 trial in November of 2024. The change in the revaluation of the liability in the years ended December 31, 2025 and December 31, 2024 is recognized in research and development expenses in the consolidated statements of operations.

Recently Issued and Adopted Accounting Pronouncements

See Note 2 to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

As a smaller reporting company, we are not required to provide the information required by this Item.

Item 8. Financial Statements and Supplementary Data.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and board of directors of Palisade Bio, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Palisade Bio, Inc. (the "Company") as of December 31, 2025 and 2024, the related consolidated statements of operations, stockholders' equity and cash flows for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2025 and 2024, and the consolidated results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures to respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ Baker Tilly US, LLP

New York, NY

March 20, 2026

We have served as the Company's auditor since 2022.

Palisade Bio, Inc.
Consolidated Balance Sheets
(in thousands, except share and per share amounts)

	December 31, 2025	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 133,385	$ 9,821
Prepaid expenses and other current assets	836	673
Total current assets	134,221	10,494
Restricted cash	55	26
Property and equipment, net	—	3
Operating lease right-of-use asset	—	84
Other noncurrent assets	68	273
Total assets	$ 134,344	$ 10,880
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 767	$ 1,105
Accrued liabilities	2,187	1,240
Accrued compensation and benefits	1,298	722
Current portion of operating lease liability	—	90
Share liability	313	—
Insurance financing debt	71	79
Total current liabilities	4,636	3,236
Warrant liability	—	2
Derivative liability	62	—
Contingent consideration obligation	266	150
Total liabilities	4,964	3,388
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Series A Convertible Preferred Stock, $0.01 par value, 7,000,000 shares authorized; 200,000 issued and outstanding at December 31, 2025 and December 31, 2024	2	2
Common stock, $0.01 par value; 300,000,000 and 280,000,000 shares authorized at December 31, 2025 and December 31, 2024, respectively; 159,444,017 and 2,768,646 shares issued and outstanding at December 31, 2025 and December 31, 2024, respectively	1,594	27
Additional paid-in capital	280,509	143,407
Accumulated deficit	(152,725)	(135,944)
Total stockholders' equity	129,380	7,492
Total liabilities and stockholders' equity	$ 134,344	$ 10,880

The accompanying notes are an integral part of these consolidated financial statements.

Palisade Bio, Inc.
Consolidated Statements of Operations
(in thousands, except share and per share amounts)

	Year Ended December 31,	
	2025	2024
Operating expenses:		
Research and development	$ 10,192	$ 9,063
General and administrative	7,864	5,796
Total operating expenses	18,056	14,859
Loss from operations	(18,056)	(14,859)
Other (expense) income:		
Interest expense	(10)	(12)
Other income, net	1,285	433
Total other income, net	1,275	421
Net loss	$ (16,781)	$ (14,438)
Basic and diluted weighted average shares used in computing basic and diluted net loss per common share	55,669,821	1,416,471
Basic and diluted net loss per common share	$ (0.30)	$ (10.19)

The accompanying notes are an integral part of these consolidated financial statements.

Palisade Bio, Inc.
Consolidated Statements of Stockholders' Equity
(in thousands, except share amounts)

	Year Ended December 31, 2025						
	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount			
Balance, December 31, 2024	200,000	$ 2	2,768,646	$ 27	$ 143,407	$ (135,944)	$ 7,492
Net loss	—	—	—	—	—	(16,781)	(16,781)
Stock-based compensation expense and related charges	—	—	—	—	3,955	—	3,955
Issuance of common stock to vendors	—	—	5,000	—	—	—	—
Issuance of common stock in connection with exercise of warrants	—	—	39,084,371	391	3,336	—	3,727
Issuance of common stock under Employee Stock Purchase Plan	—	—	26,531	1	18	—	19
Issuance of common stock in connection with July 2025 Warrant Inducement, net of issuance costs of $9,330 (Note 5)	—	—	4,318,905	43	3,370	—	3,413
Issuance of common stock and warrants in October 2025 Offering, net of issuance costs of $21,315 (Note 5)	—	—	113,240,564	1,132	126,423	—	127,555
Balance, December 31, 2025	200,000	$ 2	159,444,017	$ 1,594	$ 280,509	$ (152,725)	$ 129,380

The accompanying notes are an integral part of these consolidated financial statements.

Palisade Bio, Inc.
Consolidated Statements of Stockholders' Equity
(in thousands, except share amounts)

	Year Ended December 31, 2024						
	Preferred Stock		Common Stock		Additional Paid-in Capital*	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares*	Amount*			
Balance, December 31, 2023	200,000	$ 2	618,056	$ 6	$ 132,811	$ (121,506)	$ 11,313
Net loss	—	—	—	—	—	(14,438)	(14,438)
Stock-based compensation expense and related charges	—	—	—	—	652	—	652
Issuance of common stock to vendors	—	—	32,632	—	135	—	135
Issuance of common stock for vesting of restricted stock units, net of employee withholding tax liability	—	—	18,046	—	(25)	—	(25)
Issuance of common stock in connection with exercise of warrants	—	—	1,626,496	16	(13)	—	3
Issuance of common stock under Employee Stock Purchase Plan	—	—	2,256	—	11	—	11
Issuance of common stock in connection with February 2024 Warrant Inducement, net of issuance costs of $2,412 (Note 5)	—	—	228,162	2	2,158	—	2,160
Issuance of common stock and warrants in May 2024 Offering, net of issuance costs of $705 (Note 5)	—	—	85,100	1	3,543	—	3,544
Issuance of common stock and warrants in December 2024 Offering, net of issuance costs of $1,403 (Note 5)	—	—	158,000	2	4,135	—	4,137
Reverse stock split fractional share settlement	—	—	(102)	—	—	—	—
Balance, December 31, 2024	200,000	$ 2	2,768,646	$ 27	$ 143,407	$ (135,944)	$ 7,492

(*) Adjusted to reflect the 1-for-15 reverse stock split effected on April 5, 2024.

The accompanying notes are an integral part of these consolidated financial statements.

Palisade Bio, Inc.
Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2025	2024
Net loss	$ (16,781)	$ (14,438)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	3	3
Non-cash operating lease expense	84	114
Non-cash expense for the issuance of common stock (Note 5)	125	—
Recurring fair value measurements of liabilities	349	(54)
Payment of contingent consideration obligation	(235)	—
Issuance of common stock to vendors	—	135
Write-off of deferred equity issuance costs	75	—
Loss on disposal of property and equipment	—	4
Stock-based compensation and related charges	3,955	652
Other	(61)	—
Changes in operating assets and liabilities:		
Prepaid and other current assets and other noncurrent assets	529	750
Accounts payable and accrued liabilities	624	818
Accrued compensation and benefits	576	(56)
Operating lease liabilities	(90)	(121)
Net cash used in operating activities	(10,847)	(12,193)
Cash flows from financing activities:		
Payments on insurance financing debt	(320)	(426)
Proceeds from issuance of common stock and warrants, net of underwriting discounts and commissions	128,219	8,435
Proceeds from the exercise of warrants	7,635	2,506
Payment of warrant inducement issuance costs	(495)	(343)
Payment of equity issuance costs	(618)	(576)
Proceeds from issuance of common stock under Employee Stock Purchase Plan	19	11
Shares withheld for payment of employee withholding tax liability	—	(25)
Net cash provided by financing activities	134,440	9,582
Net increase (decrease) in cash, cash equivalents and restricted cash	123,593	(2,611)
Cash, cash equivalents and restricted cash, beginning of year	9,847	12,458
Cash, cash equivalents and restricted cash, end of year	$ 133,440	$ 9,847
Reconciliation of cash, cash equivalents and restricted cash to the balance sheets:		
Cash and cash equivalents	$ 133,385	$ 9,821
Restricted cash	55	26
Total cash, cash equivalents and restricted cash	$ 133,440	$ 9,847

The accompanying notes are an integral part of these consolidated financial statements.

Palisade Bio, Inc.
Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2025	2024
Supplemental disclosures of cash flow information:		
Interest paid	$ 10	$ 14
Supplemental disclosures of non-cash investing and financing activities:		
Equity issuance costs included in accounts payable and accrued liabilities	$ 46	$ —
Warrant inducement costs included in accounts payable and accrued liabilities	—	176
Proceeds from the issuance of common stock included in other current receivables (Note 5)	250	—
Fair value of common shares to be issued included in share liability (Note 5)	250	—
Fair value of warrants issued to solicitation agent in warrant inducements (Note 5)	233	94
Fair value of warrants issued to placement agents (Note 5)	10,870	527
Deferred equity issuance costs recognized as a reduction in additional paid-in capital from financing activities	—	37
Insurance financing debt included in prepaid and other current assets and other noncurrent assets	312	347
Incremental fair value of modified or exchanged warrants (Note 5)	8,602	2,237

The accompanying notes are an integral part of these consolidated financial statements.

Palisade Bio, Inc.
Notes To Consolidated Financial Statements

1. Organization and Business

Unless the context indicates or otherwise requires, “Palisade,” “Palisade Bio,” “the Company,” “we,” “us,” and “our” or similar designations in this Annual Report on Form 10-K ("Form 10-K") refer to Palisade Bio, Inc., a Delaware Corporation, and its subsidiaries. Any reference to “common shares” or “common stock,” refers to the Company's $0.01 par value common stock. Any reference to “Leading Biosciences, Inc.” or “LBS” refers to the Company’s operations prior to the completion of its merger with Seneca Biopharma, Inc. ("Seneca") on April 27, 2021 (the "Seneca Merger"). Any reference to “Series A Preferred Stock” refers to the Company's Series A 4.5% Convertible Preferred Stock. Any reference herein that refers to preclinical studies also refers to nonclinical studies.

Description of Business

The Company is a clinical-stage biopharmaceutical company developing next-generation, once-daily, oral phosphodiesterase-4 (“PDE4”) inhibitor prodrugs designed for targeted delivery to the terminal ileum and colon. The Company's lead clinical product candidate, PALI-2108, is being developed as a treatment for patients living with inflammatory bowel disease, or IBD, including ulcerative colitis and Crohn’s disease (“CD”).

Liquidity and Going Concern

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has a limited operating history, and the sales and income potential of the Company’s business and market are unproven. The Company has experienced net operating losses and negative cash flows from operations since its inception. The Company expects to continue to incur net operating losses in the foreseeable future. The successful transition to achieving profitability is dependent upon achieving a level of revenues adequate to support the Company’s costs. There can be no assurances that such profitability will ever be achieved. To fund its operations, the Company has historically relied on primarily equity financings.

On October 2, 2025, the Company closed on an equity offering for net proceeds to the Company of $127.6 million, consisting of gross cash proceeds of $138.0 million less underwriting discounts and commissions and other cash equity issuance costs of approximately $10.4 million (see Note 5, *Stockholders' Equity*), which as of the date that these consolidated financial statements are issued has significantly increased the Company's available working capital and its ability to fund its operations into the foreseeable future. Although the Company still anticipates incurring net operating losses and negative cash flows from operations into the foreseeable future, considered in the aggregate, management has concluded that because of the net proceeds raised from the recent equity offering in the amount of $127.6 million there is no longer a substantial doubt about the Company's ability to continue as a going concern for a period of one year following the date that these consolidated financial statements are issued.

2. Summary of Significant Accounting Policies

Basis of Presentation and Consolidation

The consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States of America (“U.S. GAAP”). Dollar amounts contained in these consolidated financial statements are in whole numbers, unless otherwise indicated.

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, LBS and Suzhou Neuralstem Biopharmaceutical Co., Ltd. All the entities are consolidated in the Company's consolidated financial statements and all intercompany activity and transactions, if any, have been eliminated.

Reverse Stock Split

On April 5, 2024, the Company effected a 1-for-15 reverse stock split of its issued and outstanding common stock (the "Reverse Stock Split"). As a result of the Reverse Stock Split, each of the Company's stockholders received one share of common stock for every 15 shares such stockholder held immediately prior to the effective time of the Reverse Stock Split. The Reverse Stock Split affected all the Company's issued and outstanding shares of common stock equally. The par value and authorized shares of the Company's common stock were not adjusted as a result of the Reverse Stock Split. The Reverse Stock Split also affected the Company's outstanding stock-based awards, common stock warrants, and other exercisable or convertible securities and resulted in the shares underlying such instruments being reduced and the exercise price or conversion price being increased proportionately. Unless otherwise noted, all common stock shares, common stock per share data and shares of common stock underlying convertible preferred stock, stock-based awards and common stock warrants included in these consolidated financial statements, including the exercise price or conversion price of such equity instruments, as applicable, have been retrospectively adjusted to reflect the Reverse Stock Split for all periods presented.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires the Company to make estimates, judgments, and assumptions that impact the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities as of the date of the balance sheet, and the reported amounts of expenses during the reporting period. The most significant estimates in the Company's consolidated financial statements relate to accrued research and development expenses and its contingent consideration obligation. Although these estimates are based on the Company's knowledge of current events and actions it may undertake in the future, actual results may materially differ from these estimates and assumptions.

Cash and Cash Equivalents

Cash and cash equivalents represent cash in readily available checking and money market accounts. The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents.

Restricted Cash

As of December 31, 2025 and December 31, 2024, the Company held restricted cash of approximately $55,000 and $26,000, respectively, in a separate restricted bank account as collateral for the Company's corporate credit card program. The Company has classified these deposits as long-term restricted cash on its consolidated balance sheets.

Deferred Equity Issuance Costs

Deferred equity issuance costs consist of the legal, accounting and other direct and incremental costs incurred by the Company related to its equity offerings, if not yet finalized as of the balance sheet date, or shelf registration statement. These costs will be charged against additional paid-in capital as a cost of the future equity issuances to which they relate. During the year ended December 31, 2025, the Company expensed approximately $75,000 of deferred equity issuance costs recognized as of December 31, 2024 that were associated with its shelf registration statement that expired in April of 2025 in general and administrative expenses in the consolidated statements of operations. During the year ended December 31, 2024, the Company charged deferred equity issuance costs of approximately $37,000 recognized as of December 31, 2023 against the additional paid-in capital recognized in conjunction with the February 2024 Warrant Inducement (see Note 5, Stockholders' Equity).

Concentration of Credit Risk

Financial instruments, which potentially subject the Company to concentration of credit risk, consist primarily of cash and cash equivalents. The Company maintains deposits in federally insured financial institutions and in money market accounts, and at times balances may exceed federally insured limits. Management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held and historically the Company has not experienced any losses in such accounts.

Fair Value of Financial Instruments

The Company follows Accounting Standards Codification ("ASC") 820, *Fair Value Measurements and Disclosures*, which among other things, defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement determined based on assumptions that market participants would use in pricing an asset or liability.

As a basis for considering such assumptions, a three-tier fair value hierarchy has been established, which prioritizes the inputs used in measuring fair value as follows:

1) Level 1: observable inputs such as quoted prices (unadjusted) in active markets for identical assets or liabilities;
2) Level 2: inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and
3) Level 3: unobservable inputs for which there is little or no market data, which require the reporting entity to develop its own assumptions, which reflect those that a market participant would use.

Further information on the fair value of the Company's financial assets and liabilities can be found at Note 4, *Fair Value Measurements*.

Derivative Financial Instruments

The Company does not use derivative instruments to hedge exposures to cash flow, market, or foreign currency risks. The Company evaluates its financial instruments to determine if such instruments are derivatives or contain features that qualify as embedded derivatives. The Company values its derivatives using the Black-Scholes option pricing model or other acceptable valuation models. Derivative instruments, if any, are valued at inception, upon events such as an exercise of the underlying financial instrument, and at subsequent reporting periods. The classification of derivative instruments, including whether such instruments should be recorded as liabilities, is reassessed at the end of each reporting period.

The Company reviews the terms of debt instruments, equity instruments, and other financing arrangements to determine whether there are embedded derivative features, including embedded conversion options that are required to be bifurcated and accounted for separately as a derivative financial instrument. Additionally, in connection with the issuance of financing instruments, the Company may issue freestanding options and common stock warrants.

The Company accounts for its common stock warrants in accordance with ASC 480, *Distinguishing Liabilities from Equity* ("ASC 480") and ASC 815, *Derivatives and Hedging* (“ASC 815”). Based upon the provisions of ASC 480 and ASC 815, the Company accounts for common stock warrants as liabilities if the warrant requires net cash settlement or gives the holder the option of net cash settlement, or if it fails the equity classification criteria. The Company accounts for common stock warrants as equity if the contract requires physical settlement or net physical settlement or if the Company has the option of physical settlement or net physical settlement and the warrants meet the requirements to be classified as equity. Common stock warrants classified as liabilities, if any, are initially recorded at fair value on the grant date and remeasured at fair value at each balance sheet date with the offsetting adjustments recorded in change in fair value of warrant liability within the consolidated statements of operations. If the terms of a common stock warrant previously classified as a liability are amended and pursuant to such amendment meet the requirements to be classified as equity, the common stock warrants are reclassified to equity at the fair value on the date of the amendment and are not subsequently remeasured. Common stock warrants classified as equity are recorded on a relative fair value basis when they are issued with other equity-classified financial instruments.

Leases

In accordance with ASC 842, *Leases*, the Company assesses contracts for lease arrangements at inception. Operating right-of-use (“ROU”) assets and liabilities are recognized at the lease commencement date equal to the present value of future lease payments using the implicit, if readily available, or incremental borrowing rate based on the information readily available at the commencement date. ROU assets include any lease payments as of

commencement and initial direct costs but exclude any lease incentives. Lease and non-lease components are generally accounted for separately and the Company recognizes operating lease expense straight-line over the term of the lease.

License Revenue

The Company uses the revenue recognition guidance established by ASC 606, *Revenue From Contracts With Customers* ("ASC 606"). When an agreement falls under the scope of other standards, such as ASC 808, *Collaborative Arrangements*, the Company will apply the recognition, measurement, presentation, and disclosure guidance in ASC 606 to the performance obligations in the agreements if those performance obligations are with a customer. As of December 31, 2025 and 2024, the Company does not have any collaborative arrangements with counterparties that are also considered customers. For arrangements that include amounts to be paid to the Company upon the achievement of certain development milestones of technology licensed by the Company, the Company recognizes such license revenue using the most likely method. At the end of each reporting period, the Company re-evaluates the probability or achievement of any potential milestones and any related constraints, and if necessary, adjusts its estimates of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenue in the period of adjustment.

Contingent Consideration Obligation

On September 1, 2023, the Company and Giiant Pharma, Inc. ("Giiant") entered into a research collaboration and license agreement (the "Giiant License Agreement")(see Note 7, *Collaborations and License Agreements*). Pursuant to the Giiant License Agreement, the Company incurred a contingent consideration obligation related to future milestone payments, which is recognized as a liability measured at fair value, and ongoing royalty payments of a mid-single-digit percentage of the adjusted gross proceeds, as defined in the Giiant License Agreement, upon the sales or sublicenses third parties of any products developed from the assets licensed under the Giiant License Agreement. Because the contingent consideration associated with the milestone payments may be settled in shares of the Company's common stock solely at the election of the Company, the Company has determined it should be accounted for under ASC 480 and accordingly the Company has recognized it as a liability measured at its estimated fair value. At the end of each reporting period, the Company re-measures the contingent consideration obligation to its estimated fair value and any resulting change is recognized in research and development expenses in the consolidated statements of operations. The Company has determined that the contingent consideration associated with the royalty payments should be recognized as a liability when they are probable and estimable, in accordance with ASC 450, *Contingencies ("ASC 450")*.

Research and Development Expenses

Research and development expenses consist of salaries and employee-related expenses including stock-based compensation costs, and, to the extent applicable, preclinical and translational science costs, clinical trial costs, costs related to acquiring and manufacturing clinical trial materials, regulatory expenses and contract services. All research and development costs are expensed as incurred pursuant to ASC 730, *Research and Development Costs*.

Research and development expenses related to clinical studies, chemistry, manufacturing and controls ("CMC") and translational science are based on estimates of the services received and efforts expended pursuant to the Company's contract arrangements. The financial terms of these contract arrangements are subject to negotiation, vary from contract to contract, and may result in uneven payment flows. Payments under some of these contracts depend on factors such as the successful enrollment of patients, site initiation and the completion of clinical milestones. The Company makes estimates of its accrued expenses as of each balance sheet date in its consolidated financial statements based on facts and circumstances known at that time. The Company accrues for research and development expenses for which the estimated services have been provided but the Company has not yet been invoiced as of the balance sheet date. There may be instances in which payments made to the Company's service providers will temporarily exceed the level of services provided and result in a prepayment of the research and development expenses. If the actual timing of the performance of services or the level of effort varies from its estimate, the Company adjusts the accrual or prepaid expense balance accordingly.

Pursuant to situations whereby the Company performs any research and development or manufacturing activities under a co-development agreement, and the co-development partner is not considered a customer under ASC 606, the Company records the expense reimbursements from the co-development partner as a reduction to research and

development expense once the reimbursement amount is approved for payment by the co-development partner. Expense payments made to Giiant pursuant to the terms of the Giiant License Agreement for qualifying development costs are expensed only as the associated research and development costs are incurred or other aspects of the drug development or related activities are achieved. In instances where the expense determined to be recognized exceeds the payments made to the Giiant, the Company recognizes an accrual of joint development expenses. In addition, there may be instances in which payments made to Giiant will temporarily exceed the level of services provided, which results in a prepayment of the joint development expenses. The Company records expense payments from Giiant, if any, as a reduction to research and development expense once the expense payments are realized or realizable, which is when Company receives the cash or has an undisputed claim to the cash that is probable of collection, pursuant to the terms of the Giiant License Agreement and the principles of ASC 450. The Company has determined that Giiant is not considered a customer under ASC 606.

Loss Contingencies

From time to time, the Company may be involved in various lawsuits, legal proceedings, or claims that arise in the ordinary course of business. In accordance with ASC 450, the Company recognizes a loss contingency provision in its financial statements when it concludes that a contingent liability is probable, and the amount thereof is estimable. For matters where a loss is not probable, or a probable loss cannot be reasonably estimated, no liability is recorded. Costs associated with the Company's involvement in legal proceedings are expensed as incurred and any insurance proceeds are recognized as a reduction in expense when they are realized or realizable, which is when Company receives the cash or has an undisputed claim to the cash that is probable of collection. Provisions for loss contingencies are recorded in Selling, general and administrative expense in the Company's consolidated statements of operations and the related accruals are recorded in Accrued liabilities in the Company's consolidated balance sheets.

Income Taxes

The Company follows ASC 740, *Income Taxes* ("ASC 740") in reporting deferred income taxes. ASC 740 requires a company to recognize deferred tax assets and liabilities for expected future income tax consequences of events that have been recognized in the Company's consolidated financial statements. Under this method, deferred tax assets and liabilities are determined based on temporary differences between financial statement carrying amounts and the tax basis of assets and liabilities using enacted tax rates in the years in which the temporary differences are expected to reverse. Valuation allowances are provided if, based on the weight of available evidence, it is more likely than not that some of or all the deferred tax assets will not be realized.

The Company accounts for uncertain tax positions pursuant to ASC 740, which prescribes a recognition threshold and measurement process for financial statement recognition of uncertain tax positions taken or expected to be taken in a tax return. If the tax position meets this threshold, the benefit to be recognized is measured as the tax benefit having the highest likelihood of being realized upon ultimate settlement with the taxing authority. The Company recognizes interest accrued related to unrecognized tax benefits and penalties in the provision for income taxes.

Stock-Based Compensation

The Company's stock-based compensation generally includes service-based restricted stock units ("RSUs"), stock options, and from time to time also includes market-based performance restricted stock units ("PSUs"). The Company accounts for forfeitures as they occur for each type of award as a reduction of expense. Stock-based compensation expense related to service-based RSUs is based on the market value of the underlying stock on the date of grant and the related expense is recognized ratably over the requisite service period, which is usually the vesting period. RSU awards generally vest over three or four years and RSU awards to directors of the Company's board of directors (the "Board") cliff vest after a period of one year. Vesting of RSUs could be accelerated in the event of retirement, disability, or death of a participant, or change in control of the Company, as defined in the individual RSU agreements or employment agreements. Pursuant to ASC 718, *Compensation - Stock Compensation* ("ASC 718"), the Company assesses for liability-classification at grant date and each subsequent balance sheet date any RSU awards that include cash settlement features whereby the award may be settled, at the Company's sole election, in shares of the Company's common stock or in cash based on the fair market value of the Company's common stock on the applicable vesting date. Pursuant to situations in which the Company concludes it has both the intent and ability to settle RSU awards that include cash settlement features in shares of the Company's common stock, based both on the RSU awards vesting schedule and perfunctory increases in the number of shares of common

stock available for issuance under the evergreen provisions of the underlying equity incentive plan, the Company classifies the RSU award as equity.

Stock option awards are generally granted with an exercise price equal to the market price of Company's stock at the date the grants are awarded and a term as determined by the Company's Board but, generally not to exceed ten-years. Stock option awards to employees vest in equal proportions each quarter over three years and stock option awards to directors of the Company's Board cliff vest after a period of one year. Vesting of stock options could be accelerated in the event of retirement, disability, or death of a participant, or change in control of the Company, as defined in the individual stock option agreements or employment agreements. Stock-based awards are valued as of the measurement date, which is the grant date, and are generally amortized on a straight-line basis over the requisite vesting period for all awards. The Company's equity incentive plans allow for the issuance of both incentive stock options and non-statutory stock options. The Company estimates the fair value of employee and non-employee stock option grants using the Black-Scholes option pricing model. The determination of the fair value of stock-based payment awards on the date of grant using the Black-Scholes option pricing model is affected by the Company's stock price as well as assumptions, which include the expected term of the award, the expected stock price volatility, risk-free interest rate, and expected dividends over the expected term of the award. Stock-based compensation expense represents the cost of the estimated grant date fair value of employee and non-employee stock option grants recognized ratably over the requisite service period of the awards, which is usually the vesting period. For PSUs with vesting subject to market conditions, the fair value of the award is determined at grant date using the Monte Carlo simulation model, and expense is recognized ratably over the derived service period regardless of whether the market condition is satisfied. The Monte Carlo simulation model considers a variety of potential future scenarios under the market condition vesting criteria, including but not limited to share prices for the Company and its peer companies in a selected market index.

The Company does not recognize any share-based compensation expense related to conditional RSUs, stock options, or PSUs that are subject to shareholder approval. When and if approval is obtained, the Company recognizes share-based compensation expense related to the conditional equity grants ratably to the vesting of shares over the remaining requisite service period.

The Company offers its employees an opportunity to participate in its shareholder approved Palisade Bio, Inc. 2021 Employee Stock Purchase Plan (the "2021 ESPP"). The Company estimates the fair value of 2021 ESPP awards on the first day of the offering period using the Black-Scholes option pricing model. The estimated fair value of 2021 ESPP awards is amortized on a straight-line basis over the requisite service period of the award. The Company reviews, and when deemed appropriate, updates the assumptions used on a periodic basis. The Company utilizes its estimated volatility in the Black-Scholes option pricing model to determine the fair value of 2021 ESPP awards.

Comprehensive Loss

Comprehensive loss is defined as a change in equity during a period from transactions and other events and circumstances from non-owner sources. The Company's comprehensive loss was the same as its reported net loss for all years presented.

Recently Adopted Accounting Pronouncements

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* ("ASU 2023-09"), which prescribes standard categories for the components of the effective tax rate reconciliation and requires disclosure of additional information for reconciling items meeting certain quantitative thresholds, requires disclosure of disaggregated income taxes paid, and modifies certain other income tax-related disclosures. The Company retrospectively adopted ASU 2023-09 in the fourth quarter of 2025. The adoption of ASU 2023-09 resulted in additional financial statement disclosures and had no impact on the Company's results of operations or financial condition. See Note 11, Income Taxes, which includes the disclosures resulting from the adoption of ASU 2023-09.

Recently Issued Accounting Pronouncements

In November 2024, the FASB issued ASU No. 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses* ("ASU 2024-03"), which is intended to improve disclosures about a public business entity's expenses by requiring disaggregated disclosure, in the notes to the financial statements, of certain categories of expenses included in the

financial statements. ASU 2024-03 is effective for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027. ASU 2024-03 may be applied either on a prospective or retrospective basis, and early adoption is permitted. The Company is currently evaluating the potential impact of the adoption of ASU 2024-03 on its consolidated financial statement disclosures.

Recently Enacted Tax Legislation

The One Big Beautiful Bill Act ("OBBBA") was enacted in the United States ("U.S") on July 4, 2025. The OBBBA legislation provides for the permanent extension of certain expiring provisions of the Tax Cuts and Jobs Act, revisions to the international tax framework and the reinstatement of favorable tax treatment for certain business provisions. Additionally, the OBBBA restores the current deduction for domestic research and experimentation ("R&E") expenses under Section 174 for businesses that have previously capitalized domestic R&E expenses for taxable years.

3. Balance Sheet Details

Prepaid expenses and other current assets consisted of the following (in thousands):

	December 31,	
	2025	2024
Prepaid insurance	$ 355	$ 384
Other current receivables	264	24
Prepaid subscriptions and fees	145	116
Prepaid software licenses	60	57
Deferred equity issuance costs	—	75
Prepaid other	12	17
	$ 836	$ 673

Accrued liabilities consisted of the following (in thousands):

	December 31,	
	2025	2024
Accrued accounts payable	$ 163	$ 109
Accrued clinical trial expenses	801	—
Accrued CMC expenses	543	606
Accrued translational science expenses	188	—
Accrued director stipends	59	59
Accrued joint development expenses (Note 7)	—	223
Accrued other	433	243
	$ 2,187	$ 1,240

4. Fair Value Measurements

The following tables reflect the Company's fair value hierarchy for its financial assets and liabilities measured at fair value on a recurring basis as of December 31, 2025 and December 31, 2024 (in thousands):

December 31, 2025	Financial Statement Classification	Level 1	Level 2	Level 3	Total
Assets:					
Money Market Funds	Cash and cash equivalents	$ 132,399	$ —	$ —	$ 132,399
Total		$ 132,399	$ —	$ —	$ 132,399
Liabilities:					
Share Liability	Share Liability	$ 313	$ —	$ —	$ 313
Derivative Liability	Derivative Liability	62	—	—	62
Contingent Consideration Obligation	Contingent Consideration Obligation	—	—	266	266
Total		$ 375	$ —	$ 266	$ 641

December 31, 2024	Financial Statement Classification	Level 1	Level 2	Level 3	Total
Assets:					
Money Market Funds	Cash and cash equivalents	$ 9,763	$ —	$ —	$ 9,763
Total		$ 9,763	$ —	$ —	$ 9,763
Liabilities:					
Warrant Liability	Warrant Liability	$ —	$ —	$ 2	$ 2
Contingent Consideration Obligation	Contingent Consideration Obligation	—	—	150	150
Total		$ —	$ —	$ 152	$ 152

Cash and Cash Equivalents

The Company invests its excess cash in money market funds that are classified as level 1 in the fair value hierarchy due to their short-term maturity of three months or less and are measured at fair value based on quoted prices in active markets for identical assets.

Share Liability and Derivative Liability

The Company's share liability and derivative liability (refer to Note 5, *Stockholders' Equity*) are each remeasured and carried at fair value at each balance sheet date based on the market value of the Company's common stock, which is a level 1 input.

Contingent Consideration Obligation

Pursuant to the Giiant License Agreement, the Company incurred a contingent consideration obligation related to future milestone payments. The Company has an obligation to make contingent consideration payments to Giiant, in either cash or shares of the Company’s common stock solely at the Company’s election, upon the achievement of development milestones. On August 2, 2024, the Company and Giiant entered into an amendment to the Giiant License Agreement, which among other things, reduced the milestone payments due to Giiant upon the achievement of certain development milestones (see Note 7, *Collaborations and License Agreements*, for further details).

The Company’s contingent consideration obligation is carried at fair value based on level 3 inputs. The fair value of the contingent consideration obligation is determined using a probability-based model that estimates the likelihood of success in achieving each of the defined milestones that is then discounted to present value using the Company's incremental borrowing rate. The fair value measurement is based on significant inputs not observable in the market and thus represents a Level 3 measurement as defined in fair value measurement accounting. The significant

assumptions used in the calculation of the fair value as of December 31, 2025 included a discount rate of 15.26% and management's updated projections of the likelihood of success in achieving the one remaining defined milestone based on empirical, published industry data.

The following table summarizes the activity of the Company's Level 3 contingent consideration obligation, which is measured at fair value on a recurring basis (in thousands):

	Year Ended December 31,	
Contingent Consideration Obligation	**2025**	**2024**
Fair value at beginning of year	$ 150	$ 204
Change in fair value during the year	351	(54)
Cash payments during the year	(235)	—
Fair value at end of year	$ 266	$ 150

On October 16, 2025, the first of the Giiant Milestone Payments (see Note 7, Collaborations and License Agreements, for further details) was achieved with the dosing of the first patient in the Company's Phase 1b clinical trial of PALI-2108 in a Fibrostenotic Crohn's Disease ("FSCD") cohort. Pursuant to the terms of the Giiant License Agreement, the Company settled this Giiant Milestone Payment in cash in the amount of $235,000 within 30 days of the date the milestone was met. The remaining amount of the contingent consideration liability of approximately $266,000 was recognized as a noncurrent liability in Contingent consideration obligation in the consolidated balance sheet as of December 31, 2025 since it is not expected to be settled within one-year of the balance sheet date. As of December 31, 2024, the entire amount of the contingent consideration obligation of approximately $150,000 was classified as a noncurrent liability in Contingent consideration obligation in the consolidated balance sheet.

Financial Instruments Not Required to be Remeasured at Fair Value

The Company's other financial assets and liabilities, including restricted cash, other current receivables, accounts payable, and accrued liabilities are not remeasured to fair value, as the carrying amount of each approximates its fair value due to the short-term nature of these instruments. The carrying value of the Company's insurance financing debt also approximates its fair value as of December 31, 2025 and December 31, 2024 due to the short-term nature of the instrument and the market rate of interest, which is based on level 2 inputs.

Assets and Liabilities Measured at Fair Value on a Nonrecurring Basis

None of the Company's non-financial assets or liabilities are recognized at fair value on a nonrecurring basis.

5. Stockholders' Equity

Classes of Stock

Common Stock

On December 3, 2025, the Company held a special meeting at which time the Company's stockholders approved an amendment to the Company's Amended and Restated Certificate of Incorporation to increase the total number of authorized shares of the Company's $0.01 par value common stock from 280,000,000 shares to 300,000,000 shares. The Company subsequently amended its Amended and Restated Certificate of Incorporation to reflect the increase. As of December 31, 2025, the Company was authorized to issue 300,000,000 shares of $0.01 par value common stock. Each share of common stock entitles the holder thereof to one vote on each matter submitted to a vote at a meeting of stockholders.

On April 5, 2024, the Company effected the Reverse Stock Split. Accordingly, each of the Company's stockholders received one share of the Company's common stock for every 15 shares of the Company's common stock that such stockholder held immediately prior to the effective time of the Reverse Stock Split. The Reverse Stock Split affected all of the Company's issued and outstanding shares of the Company's common stock equally. The Reverse Stock Split also affected the Company's outstanding stock-based awards, warrants and other exercisable or convertible securities and resulted in the shares underlying such instruments being reduced and the exercise price or conversion price being increased proportionately by the Reverse Stock Split ratio. No fractional shares were issued as a result of

the Reverse Stock Split with any fractional shares that would have otherwise resulted from the Reverse Stock Split paid in cash, at an amount equal to the resulting fractional interest in one share of the Company's common stock that the stockholder would otherwise be entitled, multiplied by the closing trading price of the Company's common stock on April 5, 2024. The amount of cash paid for fractional shares was immaterial to the Company's financial statements.

As a result of the Reverse Stock Split, on April 5, 2024 the number of issued and outstanding shares of the Company's common stock was adjusted from 12,771,015 shares to approximately 851,302 shares.

Preferred Stock

As of December 31, 2025, the Company was authorized to issue 7,000,000 shares of $0.01 par value preferred stock of which 1,000,000 shares have been designated as Series A 4.5% Convertible Preferred Stock ("Series A Convertible Preferred Stock"), of which 200,000 shares are issued and outstanding and are convertible into an aggregate of 8 shares of the Company's common stock.

Recent Equity Offerings

Crohn's and Colitis Foundation Research Program Funding Agreement

On December 17, 2025 (the “Execution Date”), the Company entered into a Research Program Funding Agreement (the “CCF Funding Agreement”) with the Crohn’s & Colitis Foundation (the “CCF”), in which the CCF agreed to provide up to a $0.5 million investment to support the Company’s Phase 1b research program related to PALI-2108.

The funding is payable in three tranches (“CCF Milestone Amount”) subject to the achievement of specified milestones. The first milestone (“CCF Milestone 1”) is in the amount of $250,000 and is due within approximately 45 days of the Execution Date. The second milestone (“CCF Milestone 2”) is in the amount of $200,000 and is due based on achievement of certain research deliverables. The third milestone (“CCF Milestone 3”) is in the amount of $50,000 and is due upon the final Phase 1b study report. CCF Milestone 1, CCF Milestone 2, and CCF Milestone 3, are collectively referred to as the “Milestone(s)”. The payments from the CCF are due within approximately 45 days of each Milestone achievement.

For each CCF Milestone payment received, within 30 days the Company must issue shares of its common stock (the “CCF Shares”) equal to the CCF Milestone Amount divided by 80% of the closing price of the Company’s common stock on the date of the respective Milestone cash receipt date.

For six years from the Execution Date, the CCF has a put option (the "CCF Put Option") on the CCF Shares whereby if the Company chooses to terminate active development of the Phase 1b research program related to PALI-2108, as defined in the CCF Funding Agreement, for reasons other than scientific failure, the CCF may require the Company to repurchase the CCF Shares at their original issue price. Pursuant to the CCF Funding Agreement, the CCF Put Option expires once the underlying CCF Shares exceed three times the closing price at which they were issued. The Company determined that although the CCF Put Option meets the definition of a derivative financial instrument pursuant to ASC 815, it also meets the equity scope exception for derivative accounting and therefore is not required to be bifurcated from the underlying CCF Shares and recognized separately.

Pursuant to ASC 480, the Company has recognized CCF Milestone 1 as a financial instrument that requires liability classification and to be initially recorded at fair value. The CCF Milestone 1 liability is expected to be settled within 75 days of the Execution Date, and therefore the subsequent change in fair value for the year ended December 31, 2025 is immaterial. On the Execution Date, the Company recognized a $250,000 other current receivable for the amount due from CCF in Prepaid and other current assets in the consolidated balance sheets. The Company recognized a $250,000 non-cash financing activity for Proceeds from the issuance of common stock included in other current receivables in the consolidated statement of cash flows for the year ended December 31, 2025. Also on the Execution Date, the Company recognized the fair value of CCF Milestone 1 of $312,500 in Share liability in the consolidated balance sheets. The Company recognized a $250,000 non-cash financing activity for the Fair Value of common shares to be issued included in share liability in the consolidated statement of cash flows for the year ended December 31, 2025. There was no change in the fair value of the Share liability between the Execution Date and December 31, 2025.

Pursuant to ASC 815, CCF Milestone 2 and CCF Milestone 3 were determined to be derivative liabilities initially recognized at fair value, with subsequent changes in fair value measured at each reporting period. On the Execution

Date, the fair value of CCF Milestone 2 was determined to be $50,000 and the fair value of CCF Milestone 3 at the Execution Date was determined to be $12,500. Both amounts are recognized in Derivative liability in the consolidated balance sheets. There was no change in the fair value of the Derivative liability between the Execution Date and December 31, 2025.

The difference between the initial fair value of the $312,500 Share liability and the $250,000 current receivable for the amount due from CCF associated with CCF Milestone 1 of $62,500, as well as the initial fair value of the derivative liabilities associated with CCF Milestone 2 and CCF Milestone 3 of $62,500, has been recognized in Other income, net, at the consolidated statement of operations for the year ended December 31, 2025 and as a Non-cash expense for the issuance of common stock in adjustments to reconcile net loss to net cash used in operating activities at the consolidated statement of cash flows for the year ended December 31, 2025.

October 2025 Offering

On October 1, 2025, the Company entered into an underwriting agreement (the "October 2025 Underwriting Agreement") pursuant to which the Company agreed to issue and sell, in an underwritten public offering by the Company (the "October 2025 Offering"), (a) 87,526,279 shares of common stock, par value $0.01 per share, at a public offering price of $0.70 per share, and (b) 83,914,280 pre-funded warrants to purchase one share of the Company's common stock, par value $0.01 per share, at a public offering price of $0.6999 per share ("October 2025 Offering Pre-funded Common Stock Warrant(s)"). The October 2025 Offering Pre-funded Common Stock Warrants were issued in lieu of shares of common stock to certain purchasers whose purchase of shares of common stock in the October 2025 Offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of the Company's outstanding common stock immediately following the closing of the offering. The October 2025 Offering Pre-funded Common Stock Warrants are exercisable immediately and may be exercised at any time until all of the pre-funded warrants are exercised in full. Each October 2025 Offering Pre-funded Common Stock Warrant has an exercise price of $0.0001 per share, and has a perpetual term. In addition, pursuant to the October 2025 Underwriting Agreement, the Company granted the sole underwriter a 45-day over-allotment option to purchase up to 25,714,285 additional shares of the Company's common stock at the public offering price, less underwriting discounts and commissions.

The Company issued common stock warrants to representatives of the sole underwriter in the October 2025 Offering to purchase an aggregate 7,878,927 shares of common stock (the "October 2025 Representative Warrants"). The October 2025 Representative Warrants have an exercise price of $1.155 per share and a term of five years from the date of issuance. The grant date fair value of the October 2025 Representative Warrants of approximately $10.9 million was recognized by the Company as an equity issuance cost, which reduced the additional paid-in capital recognized from the October 2025 Offering.

The October 2025 Offering closed on October 2, 2025 for net proceeds to the Company of $127.6 million, consisting of gross cash proceeds of $138.0 million less underwriting discounts and commissions and other cash equity issuance costs of approximately $10.4 million, which excludes the grant date fair value of the October 2025 Representative Warrants. At closing, the Company issued (a) 113,240,564 shares of common stock, par value $0.01 per share, which included the full exercise of the underwriter's over-allotment option to purchase 25,714,285 additional shares of common stock, at a public offering price of $0.70 per share, and (b) 83,914,280 October 2025 Offering Pre-funded Common Stock Warrants.

December 2024 Offering

On December 12, 2024, the Company entered into an underwriting agreement (the "December 2024 Underwriting Agreement") pursuant to which the Company agreed to issue and sell, in an underwritten public offering by the Company (the "December 2024 Offering"), (a) 158,000 Class A Units at a public offering price of $1.525 per Class A Unit (the "Class A Units"), with each Class A Unit consisting of (i) one share of the Company's common stock, par value $0.01 per share, and (ii) one warrant to purchase one share of the Company's common stock at an exercise price per share of $1.40 and a term of five years from the date of issuance ("December 2024 Offering Common Stock Warrants") and (b) 3,120,688 Class B Units at a public offering price of $1.5249 per Class B Unit (the "Class B Units", and collectively with the Class A Units, the "Units"), with each Class B Unit consisting of (i) one pre-funded warrant to purchase one share of the Company's common stock being immediately exercisable, having an exercise price of $0.0001 per share, and a perpetual term ("December 2024 Offering Pre-funded Common Stock

Warrant(s)") and (ii) one December 2024 Offering Common Stock Warrant. In addition, pursuant to the Underwriting Agreement, the Company granted the sole underwriter a 45-day over-allotment option to purchase up to 491,803 additional shares of the Company's common stock and/or December 2024 Offering Common Stock Warrants. The over-allotment option expired and was not exercised by the underwriter.

The Company issued warrants to representatives of the sole underwriter in the December 2024 Offering to purchase an aggregate 196,721 shares of common stock (the "December 2024 Representative Warrants"). The December 2024 Representative Warrants have substantially the same terms as the December 2024 Offering Common Stock Warrants, except that the exercise price of each of the December 2024 Representative Warrants is $2.51625 per share. The grant date fair value of the December 2024 Representative Warrants of approximately $0.3 million was recognized by the Company as an equity issuance cost, which reduced the additional paid-in capital recognized from the December 2024 Offering.

The December 2024 Offering closed on December 13, 2024 for net cash proceeds to the Company of approximately $4.1 million, consisting of gross cash proceeds of $5.0 million less underwriting discounts and commissions and other cash equity issuance costs of approximately $0.9 million, which excludes the grant date fair value of the December 2024 Representative Warrants and the incremental fair value of the Repriced Warrants of approximately $0.3 million, described below.

On December 12, 2024, the Company entered into a warrant amendment agreement (the "Warrant Amendment Agreement") whereby the Company, contemporaneously with and contingent with the closing of the December 2024 Offering, reduced the exercise price of 1,040,217 outstanding common stock warrants (the "Repriced Warrants") held by an investor that participated in the December 2024 Offering that expire between July 31, 2027 and May 6, 2031. The Repriced Warrants had their exercise price reduced to $1.40 per share. Other than the reduction in exercise price, the terms of the Repriced Warrants remain the same and unchanged.

The Warrant Amendment Agreement is considered a modification of the Repriced Warrants under the guidance of ASC 815-40, *Derivatives and Hedging—Contracts in Entity's Own Equity* ("ASC 815-40"). The modification is consistent with the equity issuance classification under that guidance as the reason for the Company's repricing of the warrants was to meet a condition of the holder's participation in the December 2024 Offering, which raised equity capital and generated gross cash proceeds for the Company of approximately $5.0 million. As pursuant to the guidance of ASC 480 and ASC 815 the Repriced Warrants were classified as equity instruments before and after the modification, and as the modification is directly attributable to an equity offering, the Company recognized the effect of the modification of approximately $0.3 million as an equity issuance cost charged against the additional paid-in capital recognized in the December 2024 Offering. The amount of the equity issuance cost recognized for the modification of the Repriced Warrants was determined using the Black-Scholes option pricing model as the incremental fair value of the Repriced Warrants as compared to the fair value of the warrants immediately prior to their modification.

May 2024 Offering

On May 1, 2024, the Company entered into a securities purchase agreement with an institutional investor, pursuant to which the Company sold in a private placement, (i) 85,100 shares of common stock at a purchase price per share of $6.5015, (ii) 530,142 pre-funded warrants to purchase shares common stock at a purchase price of $6.5014 per pre-funded warrant, with such pre-funded warrants being immediately exercisable, having an exercise price of $0.0001 per share, and a perpetual term, and (iii) common stock warrants to purchase 922,863 shares of the common stock at an exercise price of $6.314 per share and a term of seven years from the date of issuance (the "May 2024 Common Stock Warrants") (collectively, the "May 2024 Offering").

The Company issued warrants to the placement agent in the May 2024 Offering to purchase an aggregate 36,914 shares of common stock (the "May 2024 Placement Agent Warrants"). The May 2024 Placement Agent Warrants have substantially the same terms as the May 2024 Common Stock Warrants, except that the exercise price of each of the May 2024 Placement Agent Warrants is $10.727 per share and the term is five years from issuance. The fair value of the May 2024 Placement Agent Warrants was recognized by the Company as an equity issuance cost, which reduced the additional paid-in capital recognized from the May 2024 Offering.

The May 2024 Offering closed on May 6, 2024 for net cash proceeds to the Company of approximately $3.5 million, consisting of gross cash proceeds of $4.0 million less cash equity issuance costs of approximately $0.5

million, which excludes the grant date fair value of the May 2024 Placement Agent Warrants of approximately $0.2 million.

Common Stock Warrants and Warrant Exercises

July 2025 Warrant Inducement

On July 23, 2025, the Company entered into a warrant inducement agreement (the "July 2025 Warrant Inducement Agreement") with an accredited and institutional holder (the "July 2025 Warrant Holder") of certain of the Company's outstanding common stock warrants, including: (i) common stock warrants issued on May 10, 2022, which were transferred to the July 2025 Warrant Holder in January 2022 (the "January 2022 Warrants"), (ii) common stock warrants issued on February 1, 2024 (the "February 2024 Warrants"), (iii) common stock warrants issued on May 6, 2024 (the "May 2024 Warrants"), and (iv) the December 2024 Offering Common Stock Warrants, (collectively, the "July 2025 Existing Warrant(s)") to exercise the July 2025 Existing Warrants to purchase up to an aggregate of 4,318,905 shares of the Company's common stock. Pursuant to the July 2025 Warrant Inducement Agreement, the exercise price of each July 2025 Existing Warrant exercised was reduced from $1.40 per share to $0.9047 per share. In consideration for the immediate exercise of the July 2025 Existing Warrants, the July 2025 Warrant Holder received new unregistered warrants (the "July 2025 Replacement Warrants") to purchase shares of common stock in a private placement. Pursuant to the July 2025 Warrant Inducement Agreement, the July 2025 Warrant Holder received two July 2025 Replacement Warrants for each July 2025 Existing Warrant exercised. The July 2025 Replacement Warrants are exercisable into an aggregate of up to 8,637,810 shares of common stock beginning on the effective date of stockholder approval of the issuance of common stock shares underlying the July 2025 Replacement Warrants (the "Warrant Stockholder Approval"), at an exercise price of $0.9047 per share, and a term of exercise equal to five years from the date of Warrant Stockholder Approval (the transaction in its entirety, the "July 2025 Warrant Inducement Transaction"). The shares of common stock issuable upon the exercise of the July 2025 Replacement Warrants have subsequently been registered by the Company. On December 3, 2025, the Company convened a special meeting of stockholders at which time it received Warrant Stockholder Approval and the July 2025 Replacement Warrants became immediately exercisable.

The July 2025 Warrant Holder exercised an aggregate of 4,318,905 July 2025 Existing Warrants consisting of: (i) 3,000 January 2022 Warrants, (ii) 114,354 February 2024 Warrants, (iii) 922,863 May 2024 Warrants, and (iv) 3,278,688 December 2024 Warrants. As a result of the exercises of the July 2025 Existing Warrants, the Company issued an aggregate of 4,318,905 shares of its common stock and 8,637,810 July 2025 Replacement Warrants. The July 2025 Warrant Inducement Transaction closed on July 25, 2025 with the Company receiving net cash proceeds of approximately $3.4 million consisting of gross cash proceeds of $3.9 million, less cash equity issuance costs of approximately $0.5 million.

The July 2025 Warrant Inducement Transaction, which resulted in the lowering of the exercise price of the July 2025 Existing Warrants and the issuance of the July 2025 Replacement Warrants, is considered a modification of the July 2025 Existing Warrants under the guidance of ASC 815-40. The modification is consistent with the Equity Issuance classification under that guidance as the reason for the modification was to induce the holders of the July 2025 Existing Warrants to cash exercise their July 2025 Existing Warrants, resulting in the imminent exercise of the July 2025 Existing Warrants, which raised equity capital and generated gross cash proceeds for the Company of approximately $3.9 million. As pursuant to the guidance of ASC 480 and ASC 815-40 the July 2025 Existing Warrants and were classified as equity instruments before and after the modification, and as the modification is directly attributable to an equity offering, the Company recognized the effect of the modification of approximately $8.6 million as an equity issuance cost charged against the additional paid-in capital recognized from the associated warrant exercises. The amount of the equity issuance cost recognized for the warrant modification was determined using the Black-Scholes option pricing model as the incremental fair value of the modified July 2025 Existing Warrants and additional July 2025 Replacement Warrants issued as compared to the fair value of the original July 2025 Existing Warrants immediately prior to their modification.

The solicitation agent fees associated with the July 2025 Warrant Inducement Transaction consisted of: (i) a cash fee equal to 9% of the gross proceeds received by the Company, (ii) a common stock warrant to purchase such number of shares of common stock equal to 6% of the aggregate number of shares issued pursuant to the exercise of the July 2025 Existing Warrants, or a total of 259,134 common stock warrants, with an exercise price of $1.49 per share, and a term of five years from issuance (the "July 2025 Solicitation Agent Warrants"), and (iii) $75,000 of out-of-pocket expenses. The fair value of the July 2025 Solicitation Agent Warrants was recognized by the Company as an equity

issuance cost, which reduced the additional paid-in capital recognized from the issuance of common stock in connection with the exercise of the July 2025 Existing Warrants.

Total equity issuance costs recognized in the July 2025 Warrant Inducement Transaction of $9.3 million include cash equity issuance costs of $0.5 million, non-cash warrant modification costs of approximately $8.6 million, and non-cash issuance costs associated with the July 2025 Solicitation Agent Warrants of $0.2 million.

February 2024 Warrant Inducement

On January 30, 2024, the Company entered into warrant inducement agreements (the “February 2024 Warrant Inducement Agreements”) with certain accredited and institutional holders (collectively, the “February 2024 Warrant Holders”) of certain of the Company’s remaining outstanding common stock warrants, including: (i) common stock warrants issued on May 10, 2022 (the "May 2022 Warrants"), (ii) common stock warrants issued on January 4, 2023 (the “January 2023 Warrants”), and (iii) common stock warrants issued on April 5, 2023 (the “April 2023 Warrants”), as well as certain outstanding Series 2 warrants issued on August 16, 2022 (the "Series 2 Warrants") (collectively, the “February 2024 Existing Warrant(s)”). Pursuant to the February 2024 Warrant Inducement Agreements, the exercise price of each of the February 2024 Existing Warrants exercised was reduced to $10.97 per share. Each of the February 2024 Warrant Holders that exercised its February 2024 Existing Warrants pursuant to the February 2024 Warrant Inducement Agreements, received one replacement warrant to purchase one share of the Company's common stock (the “February 2024 Replacement Warrants”) for each February 2024 Existing Warrant exercised (in its entirety, the "February 2024 Warrant Inducement").

The February 2024 Replacement Warrants were exercisable immediately, have an original exercise price per share of $10.97, and expire five years from the date of issuance, which was February 1, 2024.

The February 2024 Warrant Holders collectively exercised an aggregate of 228,162 February 2024 Existing Warrants consisting of: (i) 4,865 May 2022 Warrants, (ii) 4,267 Series 2 Warrants, (iii) 67,511 January 2023 Warrants, and (iv) 151,519 April 2023 Warrants. As a result of the exercises of the February 2024 Existing Warrants, the Company issued an aggregate of 228,162 shares of its common stock and 228,162 February 2024 Replacement Warrants. The February 2024 Warrant Inducement closed on February 1, 2024 with the Company receiving net cash proceeds of approximately $2.2 million consisting of gross cash proceeds of $2.5 million, less cash equity issuance costs of approximately $0.3 million.

The February 2024 Warrant Inducement, which resulted in the lowering of the exercise price of the Existing Warrants and the issuance of the February 2024 Replacement Warrants, is considered a modification of the February 2024 Existing Warrants under the guidance of ASC 815-40. The modification is consistent with the Equity Issuance classification under that guidance as the reason for the modification was to induce the holders of the February 2024 Existing Warrants to cash exercise their February 2024 Existing Warrants, resulting in the imminent exercise of the February 2024 Existing Warrants, which raised equity capital and generated gross cash proceeds for the Company of approximately $2.5 million. As pursuant to the guidance of ASC 480 and ASC 815-40 the February 2024 Existing Warrants and February 2024 Replacement Warrants were classified as equity instruments before and after the modification, and as the modification is directly attributable to an equity offering, the Company recognized the effect of the modification of approximately $2.0 million as an equity issuance cost charged against the additional paid-in capital recognized from the associated warrant exercises. The amount of the equity issuance cost recognized for the warrant modification was determined using the Black-Scholes option pricing model as the incremental fair value of the modified February 2024 Existing Warrants and additional February 2024 Replacement Warrants issued as compared to the fair value of the original February 2024 Existing Warrants immediately prior to their modification.

The solicitation agent fees associated with the February 2024 Warrant Inducement consisted of: (i) a cash fee equal to 7.75% of the gross proceeds received by the Company, (ii) a common stock warrant to purchase such number of shares of common stock equal to 6% of the aggregate number shares issued pursuant to the exercise of the February 2024 Existing Warrants, or a total of 13,690 common stock warrants, with an exercise price of $10.97 per share, and a term of five years from issuance (the "February 2024 Solicitation Agent Warrants"), and (iii) $35,000 of out-of-pocket expenses. The fair value of the February 2024 Solicitation Agent Warrants was recognized by the Company as an equity issuance cost, which reduced the additional paid-in capital recognized from the issuance of common stock in connection with the exercise of the February 2024 Existing Warrants.

Total equity issuance costs recognized in the February 2024 Warrant Inducement of $2.4 million include cash equity

issuance costs of $0.3 million, non-cash warrant modification costs of approximately $2.0 million, and non-cash issuance costs associated with the February 2024 Solicitation Agent Warrants of $0.1 million.

Common Stock Warrants Outstanding and Warrant Activity

The Company accounts for the majority of its warrants as equity-classified in accordance with ASC 480 and ASC 815-40. The Company's outstanding common stock warrants that are equity-classified are included as a component of stockholders' equity based on their relative fair value on their date of issuance. Common stock warrants accounted for as liabilities in accordance with the authoritative accounting guidance are included as noncurrent liabilities in the consolidated balance sheets.

The following table summarizes the Company's outstanding and exercisable common stock warrants as of December 31, 2025:

Common Stock Warrants	Classification	Number of Warrants Outstanding and Exercisable	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)
October 2025 Offering Pre-Funded Common Stock Warrants	Equity-Classified	50,080,853	$ 0.0001	Perpetual [(1)]
July 2025 Warrant Inducement Replacement Common Stock Warrants	Equity-classified	8,637,810	0.9047	4.92
February 2024 Warrant Inducement Replacement Common Stock Warrants	Equity-classified	113,804	10.97	3.09
Series 2 Common Stock Warrants	Equity-classified	6,748	0.70	1.61
Bridge and January 2022 Common Stock Warrants	Liability-classified	2,612	2,804.69	0.62
Placement Agent, Solicitor and Representative Common Stock Warrants	Equity-classified	5,188,545	1.69	4.68
All Other Common Stock Warrants	Equity-classified	776	11,614.97	1.45
Total Warrants Outstanding and Exercisable, December 31, 2025		64,031,148	0.53	4.81 [(1)]

[(1)] The pre-funded common stock warrants outstanding as of December 31, 2025 have a perpetual term and are therefore excluded from the calculation of the weighted average remaining contractual life.

Of the outstanding common stock warrants, only the Series 2 Warrants include a down round feature whereby they are subject to price reset provisions in the event future sales of the Company's securities are sold at a price per share less than the exercise price of such warrants.

The following table summarizes all common stock warrant activity for the year ended December 31, 2025:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)
Warrants outstanding, December 31, 2024	6,745,213	$ 4.53	5.16 [(1)]
Granted	100,690,151	0.17	
Exercised	(43,403,541)	0.23	
Forfeited, expired or cancelled	(675)	5,863.33	
Warrants outstanding, December 31, 2025	64,031,148	0.53	4.81 [(1)]

[(1)] The pre-funded common stock warrants that are outstanding as of December 31, 2025 and December 31, 2024 have a perpetual term and are therefore excluded from the calculation of the weighted average remaining contractual life.

6. Equity Incentive Plans

In 2013, LBS adopted the 2013 Employee, Director, and Consultant Equity Incentive Plan, (as amended and restated, the "2013 Plan"). No further awards will be made under the 2013 Plan.

In April 2021, the Company's shareholders approved the Palisade Bio, Inc. 2021 Equity Incentive Plan (the "2021 EIP"). As of December 31, 2025, there were no shares of the Company's common stock available for future issuance as equity-based awards under the 2021 EIP, which excludes the subsequent evergreen share increase in the number of shares of common stock available for issuance under the 2021 EIP that occurred on January 1, 2026.

Also in April 2021, the Company's shareholders approved the 2021 ESPP. All employees are eligible to participate in the 2021 ESPP while employed by the Company. The 2021 ESPP permits eligible employees to purchase common stock through payroll deductions, which may not exceed $25,000 in a calendar year or 5,000 shares of the Company's shares of common stock each offering period, as defined in the 2021 ESPP, at a price equal to 85% of the fair value of the Company's common stock at the beginning or end of the offering period, whichever is lower. The 2021 ESPP is intended to qualify under Section 423 of the Internal Revenue Code. As of December 31, 2025, there have been 31,032 shares of the Company's common stock issued under the 2021 ESPP. As of December 31, 2025, there were 21,464 shares of the Company's common stock available for future issuance under the 2021 ESPP, which excludes the subsequent evergreen share increase in the number of shares of common stock available for future issuance under the 2021 ESPP that occurred on January 1, 2026.

Compensation expense associated with the 2021 ESPP for the year ended December 31, 2025 and December 31, 2024 was approximately $31,000 and $19,000, respectively.

In November 2021, the Company's compensation committee of the Board adopted the Palisade Bio, Inc. 2021 Inducement Award Plan (the "2021 Inducement Plan"). The 2021 Inducement Plan was adopted in order to grant equity-based awards to individuals not previously employed by the Company, as an inducement to join the Company. As of December 31, 2025, there were 50,341 shares of the Company's common stock available for future issuance as equity-based awards under the 2021 Inducement Plan.

Stock Options

The fair value of options granted during the years ended December 31, 2025 and December 31, 2024 is estimated as of the grant date using the Black-Scholes option pricing model using the assumptions in the following table:

	Year Ended December 31,	
	2025	2024
Weighted-average exercise price per share	$ 1.12	$ 4.54
Weighted-average expected term (years)	5.81	5.65
Weighted-average risk-free interest rate	4.38%	4.03%
Weighted-average expected dividend yield	—	—
Weighted-average volatility	127.11%	111.74%

Risk-free interest rate. The Company bases the risk-free interest rate assumption on observed interest rates appropriate for the expected term of the stock option grants.

Expected dividend yield. The Company bases the expected dividend yield assumption on the fact that it has never paid cash dividends and has no present intention to pay cash dividends.

Expected volatility. Due to the Company's limited operating history and lack of company-specific historical or implied volatility, the expected volatility assumption is based on historical volatilities of a peer group of similar companies whose share prices are publicly available. The peer group was developed based on companies in the biopharmaceutical industry.

Expected term. The expected term represents the period of time that options are expected to be outstanding. As the Company does not have sufficient historical exercise behavior, it determines the expected life assumption using the simplified method, which is an average of the contractual term of the option and its vesting period.

The following table summarizes stock option activity and related information under the 2013 Plan, the 2021 EIP and the 2021 Inducement Plan for the year ended December 31, 2025:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2024	50,674	$ 166.48		
Granted	116,600	1.12		
Exercised	—	—		
Forfeited, expired or cancelled	(14)	3,093.75		
Outstanding at December 31, 2025	167,260	50.73	8.73	$ 143
Vested and expected to vest at December 31, 2025	167,260	50.73	8.73	143
Exercisable at December 31, 2025	69,683	118.23	8.28	34

The weighted-average grant date fair value of options granted during the years ended December 31, 2025 and December 31, 2024 was $1.00 per share and $3.80 per share, respectively. The grant date fair value of the options vested during each the years ended December 31, 2025 and December 31, 2024 was approximately $0.2 million and $0.4 million, respectively.

Restricted Stock Units

The following table summarizes service-based RSU activity and related information under the 2021 EIP for the year ended December 31, 2025:

	Number of Restricted Stock Units	Weighted Average Grant Date Fair Value Per Share	Weighted Average Remaining Contractual Life (Years)
Non-vested at December 31, 2024	—	$ —	
Granted	24,851,600	1.90	
Vested	(5,000)	1.72	
Forfeited	—	—	
Non-vested at December 31, 2025	24,846,600	1.90	2.78

The grant date fair value of the RSUs vested during the year ended December 31, 2025 and December 31, 2024 was approximately $10,000 and $0.1 million, respectively.

In 2025, the Company issued certain RSUs with a cash settlement feature whereby until such time that there are sufficient shares of its common stock available under the 2021 EIP to settle all outstanding equity-based grants under the 2021 EIP, any RSUs issued with the cash settlement feature that vest prior to such time may be settled, at the Company's sole election, in shares of the Company's common stock or in cash based on the fair market value of the Company's common stock on the applicable vesting date. Upon the first occurrence of sufficient shares being available under the 2021 EIP, the settlement of the RSUs will be made exclusively in shares of the Company's common stock. As of December 31, 2025, including any shares which will become available upon future evergreens, the Company has the intent and ability to settle all of the RSU awards with a cash settlement feature in shares of the Company's common stock as of the underlying vesting dates and has therefore recognized the awards as equity-classified in accordance with ASC 718.

Performance Based Stock Units

As of December 31, 2024, a total of 2,952 PSUs remained unvested and outstanding. None of the PSUs vested during the year ended December 31, 2025 and none were forfeited during the year. As of December 31, 2025, a total of 2,952 PSUs remain unvested and outstanding with a weighted-average grant price of $22.28 per share.

Share-Based Compensation Expense

The allocation of stock-based compensation for all stock option, RSU and PSU awards is as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Research and development expense	$ 2,133	$ 263
General and administrative expense	1,791	370
Total	$ 3,924	$ 633

To reduce the ongoing administrative burden and expense associated with the quarterly vesting of the Company's service-based RSUs, on May 28, 2024, the Company's Board approved the immediate accelerated vesting of all unvested service-based RSUs issued to employees that were outstanding as of that date. The accelerated vesting was accounted for as a Type I modification under ASC 718 and accordingly, in the second quarter of 2024 the Company recognized share-based compensation expense associated with the service-based RSUs subject to immediate vesting of approximately $129,000 in general and administrative expenses and approximately $125,000 in research and development expenses.

As of December 31, 2025, the unrecognized compensation expense related to outstanding options was $0.1 million, which is expected to be recognized over a weighted-average period of approximately 1.52 years. As of December 31, 2025, unrecognized compensation expense related to outstanding service-based RSUs was $43.5 million, which is expected to be recognized over a weighted-average period of approximately 2.78 years. As of December 31, 2025, there is no unrecognized compensation expense related to outstanding PSUs.

7. Collaborations and License Agreements

Research Collaboration and License Agreement with Giiant

On September 1, 2023, the Company entered into the Giiant License Agreement whereby the Company received an exclusive, worldwide license (with the right to sublicense in multiple tiers) to develop, manufacture, and commercialize substantially all of the assets of Giiant, including: (i) the PALI-2108 compound, and (ii) the PALI-1908 compound, and the associated intellectual property around each of the foregoing (the "Giiant Licensed Assets"). The Giiant License Agreement has a perpetual term.

Pursuant to the Giiant License Agreement, the Company and Giiant established a joint development committee ("JDC"), consisting of one Giiant appointee and two Company appointees. The JDC will be responsible for: (i) overseeing the day-to-day development of the Giiant Licensed Assets through Proof of Concept (as defined below), and (ii) creation and implementation of the development plan and development budget for such development (the "Giiant Development Plan") and any amendments or updates thereto.

Prior to receiving regulatory approval to commence a Phase 1 clinical trial (as such term is defined in the Giiant License Agreement) (the "Proof of Concept"), each of the Company and Giiant was solely responsible for all costs and expenses incurred by such party for the joint development of the Giiant Licensed Assets, except as set forth in the Giiant Development Plan. Upon reaching the Proof of Concept, which occurred in October of 2024, the Company became solely responsible for all costs and expenses incurred for the development, manufacturing, regulatory and commercialization of the Giiant Licensed Assets.

For the year ended December 31, 2025, the Company recognized a net credit related to the joint development plan of approximately $1.1 million, which consisted primarily of funds received by the Company from Giiant pursuant to the joint development plan. For the year ended December 31, 2024, the Company recognized expenses of approximately $4.3 million related to the joint development plan. The Company recognized no credits to its joint development expenses for payments from Giiant for the year ended December 31, 2024. Both the expenses related to the joint development plan and any credits for funds received by the Company from Giiant are included in research and development expenses in the consolidated statements of operations.

In instances where the expense determined to be recognized exceeds the payments made to Giiant, the Company recognizes an accrual of joint development expenses. As of December 31, 2025, the Company had no joint

development expenses accrued. As of December 31, 2024, the Company accrued joint development expenses of approximately $0.2 million in Accrued liabilities in the consolidated balance sheets.

Pursuant to the Giiant License Agreement, the Company is (i) required make certain payments upon the achievement of the development milestones (as set forth in the Giiant License Agreement), in either cash or shares of the Company's common stock, at the Company's election ("Giiant Milestone Payments"), and (ii) pay ongoing royalty payments of a mid-single-digit percentage of the adjusted gross proceeds, as defined in the Giiant License Agreement, upon the sales or sublicenses of any products developed from the Giiant Licensed Assets to third parties ("Giiant Royalty Payments") (collectively, the Giiant Milestone Payments and the Giiant Royalty Payments are referred to as the "Giiant License Payments"). The Giiant License Payments are subject to a maximum payment cap in the very low eight-digit range, which will be increased or decreased on a dollar-for-dollar basis based on a formula related to the aggregate of development costs incurred by the parties ("Payment Cap"). On October 16, 2025, the Company determined that the first of the development milestones pursuant to the Giiant License Agreement, was achieved with the dosing of the first patient in the Company's Phase 1b clinical trial of PALI-2108 in a FSCD cohort. The Company settled this Giiant Milestone Payment in cash in the amount of $235,000 in the fourth quarter of 2025. As of December 31, 2025, one of the Giiant Milestone Payments remains, which could require the Company to make a payment in the low seven-digit range upon the achievement of the one remaining development milestone. There have been no other Giiant Milestone Payments made pursuant to the Giiant License Agreement.

In the event that Giiant desires to sell or assign any rights to receive the Giiant License Payments, they will be required to notify the Company of such offer or proposal ("Offer Notice"). The Company will then have a right of first refusal for thirty days from the receipt of such Offer Notice, to acquire the rights and obligations contained in such Offer Notice on the same terms.

The Company may unilaterally terminate the Giiant License Agreement for: (i) convenience, or (ii) a material breach by Giiant, that is not cured within the applicable notice period.

Giiant may unilaterally terminate the Giiant License Agreement only for a material breach by Company that is not cured within the applicable notice period provided however that upon the Payment Cap being achieved, that right will terminate and the Giiant License Agreement will become perpetual.

Co-Development and Distribution Agreement with Newsoara

Prior to the completion of the Seneca Merger, LBS entered into a co-development and distribution agreement with Newsoara, a joint venture established with Biolead Medical Technology Limited, as amended, (the "Newsoara Co-Development Agreement"). Pursuant to the Newsoara Co-Development Agreement (and subsequent assignment agreement), LBS granted or licensed Newsoara an exclusive right under certain patents to develop, use, sell, offer to sell, import, and otherwise commercialize licensed products (the "Newsoara Licensed Products") for any and all indications in the People's Republic of China, including the regions of Hong Kong and Macao, but excluding Taiwan (the "Territory"). The Newsoara Licensed Products only include the drug asset LB1148, which the Company ceased developing in August of 2023. The right includes the right to grant sublicenses to third parties, subject to LBS' written consent, provided that both parties agreed that Newsoara would be permitted to use a certain partner for development purposes. The Newsoara Co-Development Agreement obligates Newsoara to initially use LBS as the exclusive supplier for all Newsoara's requirements for Newsoara Licensed Products in the Territory. During the term of the Newsoara Co-Development Agreement, Newsoara may request to manufacture the Newsoara Licensed Products in the Territory, subject to satisfying certain conditions to LBS' reasonable satisfaction. LBS is obligated to approve Newsoara manufacturing rights without undue refusal or delay. The Company records the expense reimbursements from Newsoara for any research and development or manufacturing activities it performs under the Newsoara Co-Development Agreement as a reduction to research and development expenses once the reimbursement amount is approved for payment by Newsoara.

In consideration of the rights granted to Newsoara under the Newsoara Co-Development Agreement, Newsoara paid LBS a one-time upfront fee of $1.0 million. In addition, Newsoara is obligated to make (i) payments of up to $6.75 million in the aggregate upon achievement of certain regulatory and commercial milestones, (ii) payments in the low six-digit range per licensed product upon achievement of a regulatory milestone, and (iii) tiered royalty payments ranging from the mid-single-digit to low-double-digit percentage range on annual net sales of Licensed Products, subject to adjustment to the royalty percentage in certain events, including a change of control, the expiration of

certain patents rights, and royalties paid by Newsoara third parties. To date, Newsoara has met all of its payment obligations under the Newsoara Co-Development Agreement.

During the years ended December 31, 2025 and December 31, 2024, the Company recognized no license revenue from Newsoara under the Newsoara Co-Development Agreement.

The Newsoara Co-Development Agreement will expire upon the expiration date of the last valid claim of any licensed patent covering the Newsoara Licensed Products in the Territory. In addition, the Newsoara Co-Development Agreement can be terminated (i) by either party for the other party's material breach that remains uncured for a specified time period after written notice or for events related to the other party's insolvency, (ii) by LBS if Newsoara challenges or attempts to interfere with any licensed patent rights and, (iii) by Newsoara for any reason upon specified prior written notice.

License Agreements with the Regents of the University of California

Prior to the Seneca Merger, the Company has entered into three license agreements, as amended, with the Regents of the University of California ("Regents") for exclusive commercial rights to certain patents, technology and know-how related to LB1148. Concurrent with the Company's decision to terminate the development of LB1148, on October 20, 2023 the Company terminated two of its license agreements with Regents. As of December 31, 2025, the only license agreement remaining with Regents is that entered into with LBS in August 2015, as amended in December 2019 and September 2022 (the "2015 UC License"). The 2015 UC License was retained for the sole purpose of maintaining the Newsoara Co-Development Agreement under which the Company may receive future milestone or royalty payments through the term of the license. Accordingly, pursuant to the 2015 UC License, the Company is obligated to pay a percentage of non-royalty licensing revenue it receives from Newsoara under the Newsoara Co-Development Agreement to Regents ranging from 30 percent to 35 percent of one-third of the upfront payment and milestone payments received from Newsoara. During the year ended December 31, 2025, the Company recognized no sublicense fees or license maintenance fees due to Regents. During the year ended December 31, 2024, the Company recognized no sublicense fees and license maintenance fees of approximately $16,000 due to Regents. License maintenance fees are recognized in research and development expenses in the consolidated statements of operations.

The 2015 UC License will expire upon the expiration date of the longest-lived patent right licensed under the 2015 UC License. The Regents may terminate the 2015 UC License if: (i) a material breach by the Company is not cured within 60 days, (ii) the Company files a claim asserting the Regents licensed patent rights are invalid or unenforceable, or (iii) the Company files for bankruptcy. The Company also has the right to terminate the 2015 UC License at any time upon at least 90 days' written notice.

Contingent Value Right

Immediately prior to the closing of the Seneca Merger, Seneca issued each share of its common stock held by Seneca stockholders of record, one contingent value right ("CVR"). The CVR entitled the holder (the "CVR Holder") to receive, pro rata with the other CVR Holders, 80% of the net proceeds, if any and subject to certain minimum distribution limitations ("CVR Payment Amount"), received from the sale or licensing of the intellectual property owned, licensed or controlled by Seneca immediately prior to the closing of the Seneca Merger (the "Legacy Technology"); provided however that the CVR Holders are only entitled to receive such CVR Payment Amount if the sale or licensing of such Legacy Technology occurred on or before October 27, 2022 ("Legacy Monetization"). Pursuant to the terms of the CVR agreement ("CVR Agreement"), CVR Holders entitlement to receive CVR Payment Amounts expired on April 27, 2025. There were no CVR Payments made to any of the CVR Holders pursuant to the CVR Agreement.

NSI-189 – Exclusive License and Subsequent Exercise of Purchase Option

Prior to the Seneca Merger, Seneca exclusively licensed certain patents and technologies, including a sublicense covering a synthetic intermediate, of the Company's NSI-189 assets ("189 License"), along with a purchase option through December 16, 2023 ("Purchase Option"). On October 22, 2021, Alto Neuroscience ("Alto") agreed to terms of an early exercise of the Purchase Option under the 189 License and entered into an asset transfer agreement ("ATA"). Alto is a U.S. based public, clinical-stage biopharmaceutical company with a mission to redefine psychiatry by leveraging neurobiology to develop personalized and highly effective treatment options.

Pursuant to the ATA, Alto will be required to pay the Company up to an aggregate of $4.5 million upon the achievement of certain development and regulatory approval milestones for NSI-189 (or a product containing or otherwise derived from NSI-189), which is now known as ALTO-100. If Alto sells or grants to a third party a license to the patents and other rights specific to ALTO-100 prior to the achievement of a specified clinical development milestone, Alto will be required to pay to the Company a low-double digit percentage of any consideration received by Alto from such license or sale, provided that the maximum aggregate consideration Alto will be required to pay to the Company under the ATA, including the upfront payment and all potential milestones and transaction-related payments, will not exceed $5.0 million.

On October 22, 2024, Alto announced that its Phase 2b study of ALTO-100 in patients with major depressive disorder (MDD) did not meet its primary endpoint. Notwithstanding, ALTO-100 is being evaluated as an adjunctive treatment in a Phase 2b study in bipolar depression with topline data expected in the second half of 2026. Upon the enrollment of a patient in a Phase 3 clinical trial of ALTO-100, if it occurs, a milestone payment of $1.5 million will be due to the Company from Alto under the ATA.

NSI-532.IGF-1

On October 27, 2022, the Company entered an agreement to license NSI-532.IGF-1 to the Regents of the University of Michigan ("University of Michigan") for maintaining NSI-532.IGF-1 cell lines, continued development, maintaining patent protection, and seeking licensees. The Company received no upfront fees for the license. NSI-532.IGF-1 is a preclinical cell therapy being investigated as a potential therapy for prevention and treatment of Alzheimer’s disease. The University of Michigan shall bear 100% of the costs for patent filing, prosecution, maintenance, and enforcement of the patent rights. The Company will receive 50% of net revenues received by the University of Michigan from the licensing of patent rights through the last-to-expire patent in patent rights, unless otherwise earlier terminated, less all reasonable and actual out-of-pocket costs incurred in the litigation of patent rights.

8. Commitments and Contingencies

Corporate Office Lease

The Company was party to a non-cancelable facility operating lease (the "Corporate Office Lease") of office space for its corporate headquarters in Carlsbad, California. The initial contractual term was for 39-months commencing on June 1, 2022 and the lease expired on August 31, 2025. The Company has determined it will not enter into a new lease for its corporate office space.

The Company recognized operating lease expense associated with its Corporate Office Lease of approximately $87,000 and $130,000 for the years ended December 31, 2025 and December 31, 2024, respectively.

Insurance Financing Arrangement

In June of 2025, the Company entered an agreement to finance an insurance policy that renewed in May of 2025. The financing arrangement entered in June of 2025 has a stated annual interest rate of 7.82% and is payable over a 9-month period with the first payment payable on June 30, 2025. The insurance financing arrangement is secured by the associated insurance policy. As of both December 31, 2025 and December 31, 2024, the aggregate remaining balance under the Company's insurance financing arrangements in place at each time was approximately $0.1 million and is included in Insurance financing debt in the consolidated balance sheets.

Other than the remaining insurance financing arrangement payments due in 2026, as of December 31, 2025 the Company has no other minimum debt payments required in 2026 or thereafter.

Legal Proceedings

From time to time, the Company may be involved in various lawsuits, legal proceedings, or claims that arise in the ordinary course of business. Management believes there are no claims or actions pending against the Company through December 31, 2025, which will have, individually or in the aggregate, a material adverse effect on its business, liquidity, financial position, or results of operations. Litigation, legal proceedings or claims, however, are

subject to inherent uncertainties, and an adverse result in such matters may arise from time to time that may harm the Company's business.

9. Net Loss Per Share

Basic and Diluted Net Loss Per Common Share

Basic net loss per common share is computed by dividing net loss available to common stockholders by the weighted-average number of shares of common stock outstanding during the period. Diluted net loss per share is calculated by dividing the net loss available to common stockholders by the weighted-average number of shares of common stock outstanding during the period, plus any potentially dilutive common shares, consisting of stock-based awards and equivalents, and common stock warrants. For purposes of this calculation, stock-based awards and equivalents and common stock warrants are considered to be potential common shares and are only included in the calculation of diluted net loss per common share when their effect is dilutive.

The Company's Series A Convertible Preferred Stock and certain of the Company's outstanding common stock warrants contain non-forfeitable rights to dividends with the common stockholders, and therefore are considered to be participating securities. The Series A Convertible Preferred Stock and the common stock warrants do not have a contractual obligation to fund the losses of the Company; therefore, the application of the two-class method is not required when the Company is in a net loss position but is required if the Company is in a net income position. When in a net income position, diluted net earnings per common share is computed using the more dilutive of the two-class method or the if-converted and treasury stock methods.

Pursuant to the October 2025 Offering, on October 2, 2025, the Company issued the October 2025 Offering Pre-Funded Common Stock Warrants. Pursuant to the December 2024 Offering, on December 13, 2024, the Company issued the December 2024 Offering Pre-funded Common Stock Warrants. See Note 5, *Stockholders' Equity,* for further discussion of each of these financing transactions. Both the October 2025 Offering Pre-funded Common Stock Warrants and the December 2024 Offering Pre-funded Common Stock Warrants were determined to be equity-classified in accordance with ASC 480 and ASC 815. As of December 31, 2025 and December 31, 2024, 50,080,853 of the October 2025 Offering Pre-funded Common Stock Warrants and 2,027,000 of the December 2024 Offering Pre-funded Common Stock Warrants, respectively, remained unexercised. Pursuant to the guidance of ASC 260-10, the Company concluded that because the equity-classified pre-funded warrants were immediately exercisable for little or no cash consideration due to the non-substantive stated exercise price, all the necessary conditions for issuance of the underlying common shares had been met when the pre-funded warrants were issued. Therefore, the underlying common shares for the unexercised portion of the October 2025 Offering Pre-funded Common Stock Warrants have been included in the denominator for the calculation of basic and dilutive net loss per common share for the year ended December 31, 2025, and the underlying common shares for the unexercised portion of the December 2024 Offering Pre-funded Common Stock Warrants have been included in the denominator for the calculation of basic and dilutive net loss per common share for the year ended December 31, 2024.

As the Company was in a net loss position for all periods presented, basic and diluted net loss per common share for both the years ended December 31, 2025 and December 31, 2024 was calculated under the if-converted and treasury stock methods. For both the years ended December 31, 2025 and December 31, 2024, basic and diluted net loss per common share were the same as all common stock equivalents other than the pre-funded warrants discussed above were anti-dilutive for both years.

The following table presents the calculation of weighted average shares used to calculate basic and diluted net loss per common share (in thousands, except share and per share amounts):

	Year Ended December 31,	
	2025	2024
Basic and diluted net loss per common share:		
Net loss	$ (16,781)	$ (14,438)
Weighted average shares used in calculating basic and diluted net loss per common share	55,669,821	1,416,471
Basic and diluted net loss per common share	$ (0.30)	$ (10.19)

The following potentially dilutive securities were excluded from the calculation of diluted net loss per share because their effects would be anti-dilutive:

	December 31,	
	2025	2024
Stock options	167,260	50,674
Service-based and performance-based restricted stock units	24,849,552	2,952
Common stock warrants	13,950,295	4,718,213
Series A Convertible Preferred Stock	8	8
Total	38,967,115	4,771,847

10. Employee Benefits

The Company participates in a defined contribution 401(k) plan adopted by LBS effective June 20, 2016 (the "LBS 401(k) Plan"). All employees are eligible to participate in the plan beginning on the first day of employment. Under the terms of the plan, employees may make voluntary contributions as a percent of compensation. No matching contributions were made by the Company the years ended December 31, 2025 and December 31, 2024.

Effective as of January 1, 2026, the Company's compensation committee of its Board amended the LBS 401(k) Plan to provide for the Company to make matching contributions in an amount equal to 100% of employees voluntary deferral contributions that are not over 6% of eligible compensation.

The Company's common stock is not an investment option available to participants in the 401(k) Plan.

11. Income Taxes

The Company has no current or deferred income taxes as of December 31, 2025 and December 31, 2024.

Income taxes vary from the statutory federal income tax rate applied to loss before income taxes as follows (in thousands):

	Year Ended December 31,			
	2025		2024	
	Amount	Percent	Amount	Percent
Statutory federal income tax rate of 21 percent applied to loss before income taxes	$ (3,524)	21.0%	$ (3,032)	21.0%
Nontaxable or nondeductible items:				
Stock-based compensation	45	(0.3)%	371	(2.6)%
Executive compensation	429	(2.6)%	12	(0.1)%
Other permanent differences	32	(0.2)%	1	(0.0)%
Expiration of tax attributes	583	(3.5)%	184	(1.3)%
Adjustment to deferred tax balances	4,397	(26.2)%	—	0.0%
Other	50	(0.3)%	(49)	0.3%
Valuation allowance	(2,012)	12.0%	2,513	(17.4)%
	$ —	0%	$ —	0%

Deferred income tax assets and liabilities arising from differences between accounting for financial statement purposes and tax purposes, less valuation reserves at year end are as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Deferred tax assets:		
Accrued expenses	$ 195	$ 122
Depreciation	177	82
Lease liability	—	25
Net operating loss carryforwards	20,737	27,383
Stock compensation	1,822	1,216
Capitalized research and development costs	4,454	3,771
Total deferred tax assets	27,385	32,599
Deferred tax liabilities:		
Operating right-of-use asset	—	23
Prepaid expense	99	108
Total deferred tax liabilities	99	131
Net deferred tax asset	27,286	32,468
Valuation allowance	(27,286)	(32,468)
Net deferred taxes	$ —	$ —

Deferred tax assets and liabilities are recognized for temporary differences and unused tax losses to the extent that realization of the related tax benefits is more-likely-than-not. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods when the deferred tax assets become deductible. After considering the history of operating losses and uncertainty regarding its ability to generate positive pre-tax income in 2026 and beyond, the Company has concluded that it is not-more-likely-than-not that its deferred tax assets will be realized, and therefore maintains a full valuation allowance on all deferred tax assets.

The valuation allowance decreased $5.2 million during the year ended December 31, 2025 and increased $3.5 million during the year ended December 31, 2024.

As of December 31, 2025, the Company had federal net operating loss ("NOL") carryforwards of approximately $93.8 million and state NOL carryforwards of approximately $14.9 million. Of the total amount of federal NOL carryforwards, approximately $85.8 million arose in tax years beginning after December 31, 2017 and will carry forward indefinitely. The federal NOL carryforwards arising in tax years beginning before January 1, 2018 of approximately $8.0 million will begin to expire in 2026 unless previously utilized. The Company’s state NOL carryforwards as of December 31, 2025 may be carried forward for 20 years, and will begin to expire in 2027.

Pursuant to the provisions of the Internal Revenue Code ("IRC"), the Company’s NOL and tax credit carryforwards and certain other attributes are subject to review and possible adjustment by the Internal Revenue Service ("IRS") and state tax authorities. NOL and tax credit carryforwards may be subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three-year period in excess of 50 percent, as defined under Sections 382 and 383 of the IRC, as well as similar state provisions. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. Further, when there are multiple ownership changes, all resulting limitations must be applied to the attributes that existed prior to the ownership change. Since its inception, the Company has completed the Seneca Merger and several equity offerings, including the October 2025 Offering, which may have resulted in a change in control as defined by Sections 382 and 383 of the IRC, or could result in a change in control in the future. The Company has not performed a complete IRC Section 382 and 383 analysis for all relevant tax years regarding the limitation of net operating losses. Although the NOL deferred tax asset does reflect the limitation resulting from both the Seneca Merger and the October 2025 Offering, there could be further limitations due to prior changes in control. Due to the existence of a full valuation allowance, however, changes in the NOLs included as deferred tax assets on the Company’s consolidated balance sheets would have no impact on the Company's effective tax rate.

The Company files income tax returns in the U.S. federal jurisdiction and California. Because of the NOLs, the Company is subject to U.S. federal examinations for tax years 2007 and forward, and for examinations from state taxing authorities for tax years 2008 and forward.

The Company accounts for taxation under ASC 740, which clarifies the accounting for uncertain tax positions. ASC 740 requires that the Company recognize the impact of a tax position in its consolidated financial statements if the position is more-likely-than-not to be sustained upon examination based on the technical merits of the position. The Company did not have any uncertain income tax positions as of December 31, 2025 and 2024.

ASC 740 requires the Company to accrue interest and penalties where there is an underpayment of taxes based on the Company's best estimate of the amount to ultimately be paid. The Company identified no unrecorded material uncertain tax positions as of December 31, 2025 and 2024, consequently no interest or penalties have been accrued by the Company in either period. The Company does not anticipate a significant change to its unrecognized tax benefits within the next 12 months.

12. Segment Information

The Company operates as one operating and reportable segment, focused on the research and development of novel therapeutics for patients, including the advancement of PALI-2108 through clinical trials. The Company did not aggregate multiple operating segments into its one operating segment. The Company’s chief operating decision maker (“CODM”) is its chief executive officer.

The Company's CODM uses Net loss that is reported on the consolidated statements of operations for the purposes of assessing performance, allocating resources and planning, monitoring budget versus actual results, and forecasting future periods. The Company’s CODM views specific program spend within research and development expenses, research and development spend that is not allocated to specific programs, as well as general and administrative expenses as significant segment expenses. As a pre-product revenue company, the CODM considers budget versus actual results for expenses that are deemed significant and cash forecast models for assessing performance and to decide the level of investment in the Company’s operating and capital allocation activities.

In addition to significant expense categories included in Net loss, the Company regularly provides disaggregated significant expense amounts that comprise operating expenses to the CODM to assist when managing the Company's single reporting segment. A reconciliation to consolidated operating expenses for the years ended December 31, 2025 and 2024 is included in the table below (in thousands):

	Year Ended December 31,	
	2025	2024
PALI-2108 program expenses	$ 5,516	$ 7,070
Legacy program expenses	—	155
Other research and development expenses	4,960	2,156
Other general and administrative expenses	7,580	5,478
Total operating expenses	$ 18,056	$ 14,859

PALI-2108 program expenses are those expenses directly related with the development of the Company's only asset currently under development, PALI-2108. Legacy program expenses are those expenses directly related to its legacy assets, primarily LB1148, which the Company ceased developing in August of 2023. Other research and development expenses includes primarily salary and employee-related costs and benefits and research and development facility expenses, which are not allocated to specific programs, and non-cash loss or gain associated with changes in the fair value of the Company's contingent consideration obligation. Other general and administrative expenses consist primarily of salary and employee-related costs and benefits, legal professional fees expenses, investor and public relations expenses, accounting and audit services, insurance costs, director and committee fees, and general corporate expenses. Excluded from other general and administrative expenses are intellectual property expenses and business development expenses that are allocated to program expenses.

For the years ended December 31, 2025 and 2024, the other segment items that the Company used to aggregate Total operating expenses to arrive at Net Loss as shown on the consolidated statement of operations include Interest expense and Other income, net.

The Company does not provide separate segment asset information to the CODM because the CODM does not review segment assets at a different asset level or category than those shown on the consolidated balance sheets. All of the Company's assets are located in the U.S.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Our management, with the participation of our Chief Executive Officer, who is also our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2025. Based upon the evaluation, our Chief Executive Officer concluded that, as of December 31, 2025, our disclosure controls and procedures were not effective at a reasonable assurance level as a result of the material weakness that existed in our internal control over financial reporting, as described below.

However, our management, including our Chief Executive Officer, has concluded that, notwithstanding the identified material weakness in our internal control over financial reporting, the consolidated financial statements in this Annual Report on Form 10-K fairly present, in all material respects, our financial position, results of operations and cash flows for the periods presented in conformity with U.S. GAAP.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as such term as defined in Exchange Act Rule 13a-15(f). Internal control over financial reporting is a process designed under the supervision and with the participation of our management, including our principal executive officer, who is also our principal financial officer, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with U.S. GAAP.

Material Weakness in Internal Control over Financial Reporting

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that a reasonable possibility exists that a material misstatement of our annual or interim consolidated financial statements would not be prevented or detected on a timely basis.

As previously disclosed, during the quarter ended June 30, 2021, we identified a material weakness in our internal controls over financial reporting due to a lack of controls in the financial closing and reporting process, including a lack of segregation of duties and the documentation and design of formalized processes and procedures surrounding the creation and posting of journal entries and account reconciliations. This material weakness contributed to a material weakness in our control activities based on the criteria set forth in the Committee of Sponsoring Organizations 2013 Framework. If not remediated, or if we identify further material weaknesses in its internal controls, our failure to establish and maintain effective disclosure controls and procedures and internal control over financial reporting could result in material misstatements in our consolidated financial statements and a failure to meet its reporting and financial obligations.

As described below, management has begun designing the plan to executing the remediation actions to address the material weakness and further actions are ongoing as of December 31, 2025. The material weakness continues to be present as of December 31, 2025.

Remediation Efforts related to the Material Weakness

Management, with oversight from our Audit Committee of the Board, is actively engaged in remediation efforts to address the material weaknesses identified in the management's evaluation of internal controls and procedures. The remediation efforts summarized below, which have been or are in the process of being implemented, are intended to address the identified material weakness.

(i) We have hired or contracted with additional finance and accounting employees with appropriate experience, certification, education and training.

(ii) We have implemented new accounting and finance management software effective July 1, 2022, which is intended to eliminate some of the existing deficiencies in our internal control environment. The information technology general controls implemented with the new accounting and finance management software will be tested for operating effectiveness.

(iii) We are in the process of updating our formal accounting policies, procedures and controls, including preparation and review of account reconciliations, review of journal entries, and controls over period end financial reporting.

(iv) We have identified and implemented controls to address known segregation of duties deficiencies in our current control environment. The controls implemented to remediate known segregation of duties deficiencies identified will be documented and tested for operating effectiveness.

(v) We will continue to implement, as needed, additional key internal controls designed to address the potential risks identified in our key business processes. Any additional controls implemented will be tested for operating effectiveness.

We believe that remediation steps taken to date have allowed us to address a number of the deficient controls within our internal control environment. However, the material weakness identified above will not be considered remediated until we complete the design and implementation of our remediation plans and demonstrate the operating effectiveness of our remediation efforts over a sufficient period of time and management has concluded, through testing, that these controls are operating effectively.

Changes in Internal Control Over Financial Reporting

Other than those as a result of the remediation efforts described above, there were no changes in the Company's internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) during the quarter ended December 31, 2025 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Item 9B. Other Information.

Not applicable.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Certain information required by Part III is omitted from this Annual Report on Form 10-K since we intend to file our definitive proxy statement for our 2026 Annual Meeting of Stockholders (the "2026 Proxy Statement"), pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended, not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and certain information to be included in the Proxy Statement is incorporated herein by reference.

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item is to be included in the 2026 Proxy Statement in the sections entitled “Election of Directors - Nominees for Election to the Board of Directors,” “Corporate Governance - Code of Ethics,” “Corporate Governance - Insider Trading Policy,” “Corporate Governance - Board of Directors,” “Corporate Governance - Board of Directors,” “Corporate Governance - Board Meetings,” “Corporate Governance - Board Leadership Structure,” “Corporate Governance - Information Regarding Committees of the Board of Directors,” “Director Compensation,” and, to the extent applicable, “Delinquent Section 16(a) Reports.”

Item 11. Executive Compensation.

The information required by this item will be contained in the 2026 Proxy Statement under the captions “Executive Compensation” and "Director Compensation" and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item will be contained in the 2026 Proxy Statement under the captions “Security Ownership of Certain Beneficial Owners and Management" and "Securities Authorized for Issuance Under Equity Compensation Plans" and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item will be contained in the 2026 Proxy Statement under the captions “Certain Relationships and Related Transactions,” and “Corporate Governance - Independent Directors” and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

Our independent registered public accounting firm is Baker Tilly US, LLP, New York, New York, PCAOB ID #23.

The information required by this item is to be included in our 2026 Proxy Statement under the caption “Independent Registered Public Account Firm" and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a)(1) Financial Statements.

The consolidated financial statements and supplementary data required by this item are set forth under Item 8 above.

(a)(2) Financial Statement Schedules.

All schedules have been omitted because they are not required or because the required information is given in the consolidated financial statements or notes thereto.

(a)(3) Exhibits.

The exhibits listed in the Exhibit Index below are filed or incorporated by reference as part of this Annual Report on Form 10-K.

Exhibit Index

Exhibit Number	Description of Document
2.1†	Agreement and Plan of Merger, dated as of December 16, 2020, by and among Seneca Biopharma, Inc., Leading BioSciences, Inc. and Townsgate Acquisition Sub 1, Inc. (Incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on December 21, 2020).
3.1	Amended and Restated Certificate of Incorporation of the Registrant (Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on April 27, 2021).
3.2	Certificate of Designation of Preferences, Rights and Limitations of Series A 4.5% Convertible Preferred Stock (Incorporated by reference to Exhibit 3.01 to the Registrant's Current Report on Form 8-K, filed with the SEC on December 12, 2016).
3.3	Amended and Restated Bylaws of the Registrant (Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on March 6, 2024).
3.4	Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock (Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on August 16, 2022).
3.5	Amendment to Amended and Restated Certificate of Incorporation of Palisade Bio, Inc., effective November 15, 2022 (Incorporated by reference to Exhibit 3.01(i) to the Registrant's Current Report on Form 8-K, filed with the SEC on November 16, 2022).
3.6	Amendment to the Amended and Restated Certificate of Incorporation of Palisade Bio, Inc. effective April 5, 2024 (Incorporated by reference to Exhibit 3.01(i) to the Registrant's Current Report on Form 8-K, filed with the SEC on April 5, 2024).
3.7	Amendment to the Amended and Restated Certificate of Incorporation of Palisade Bio, Inc. effective December 3, 2025 (Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed with the SEC on December 4, 2025).
4.1	Reference is made to Exhibits 3.1, 3.2 and 3.3.
4.2	Description of Securities (incorporated by reference to Exhibit 4.2 to the Registrant's Form 10-K, filed with the SEC on March 17, 2022).
4.3	Specimen Common Stock Certificate. (Incorporated by reference to Exhibit 4.3 to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 17, 2022).
4.4	Form of Series A Preferred Stock Certificate (Incorporated by reference to Exhibit 4.01 to the Registrant's Current Report on Form 8-K, filed with the SEC on September 12, 2016).
4.5	Letter Agreement from January 2020 Offering (Incorporated by reference to Exhibit 10.01 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on January 22, 2020)
4.6	Form of Series O Pre-Funded Warrant from July 2019 Offering (Incorporated by reference to Exhibit 4.45 to the Registrant's Registration Statement on Form S-1/A (File No. 333-232273), filed with the SEC on July 24, 2019)
4.7	Form of Warrant to Purchase Shares of Common Stock of Leading BioSciences, Inc. (Incorporated by reference to Exhibit 4.30 to the Registrant's Registration Statement on Form S-4 (File No. 333-251659), originally filed with the SEC on December 23, 2020, as amended).
4.8	Form of Bridge Warrant of Leading BioSciences, Inc. (Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on December 21, 2020).
4.9	Form of Equity Warrant of Leading BioSciences, Inc. (Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on December 21, 2020).
4.10†	Registration Rights Agreement, by and between Seneca Biopharma, Inc. and the investor party thereto, dated December 16, 2020 (Incorporated by reference to Exhibit 4.3 to the Registrant's Current Report on Form 8-K, filed with the SEC on December 21, 2020).

4.11	Waiver Agreement, dated as of July 21, 2021, by and between Palisade Bio, Inc. and Altium Growth Fund, LP (Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on July 22, 2021).
4.12	Warrant, dated as of July 21, 2021, issued to Altium Growth Fund, LP (Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on July 22, 2021).
4.13	Securities Purchase Agreement, dated as of August 19, 2021, by and between Palisade Bio, Inc. and Yuma Regional Medical Center (Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on August 24, 2021).
4.14	Warrant, dated as of August 19, 2021, issued to Yuma Regional Medical Center (Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on August 24, 2021).
4.15	Form of Common Stock Purchase Warrant (Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on May 6, 2022).
4.16	Form of Placement Agent Warrant (Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on May 6, 2022).
4.17	Form of Series 2 Common Stock Warrant (Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on August 16, 2022).
4.18	Warrant Agency Agreement dated August 16, 2022, by and between Palisade Bio, Inc. and American Stock Transfer and Trust Company, LLC. (Incorporated by reference to Exhibit 4.3 to the Registrant's Current Report on Form 8-K, filed with the SEC on August 16, 2022).
4.19	Form of Underwriter Warrant issued August 16, 2022 (Incorporated by reference to Exhibit 4.33 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on November 14, 2022).
4.20	Form of Warrant issued in January 2023 Private Placement (Incorporated by reference to Exhibit 4.03 to the Registrant's Current Report on Form 8-K, filed with the SEC on January 4, 2023).
4.21	Form of Placement Agent Warrant issued in January 2023 Private Placement (Incorporated by reference to Exhibit 4.04 to the Registrant's Current Report on Form 8-K, filed with the SEC on January 4, 2023).
4.22	Form of Warrant issued in April 2023 Private Placement (Incorporated by Reference to Exhibit 4.02 to the Registrant's Current Report on Form 8-K, filed with the SEC on April 5, 2023).
4.23	Form of Placement Agent Warrant issued in April 2023 Private Placement (Incorporated by reference to Exhibit 4.03 to the Registrant's Current Report on Form 8-K filed with the SEC on April 5, 2023).
4.24	Form of Placement Agent Warrant issued in September 2023 Private Placement (Incorporated by reference to Exhibit 4.01 to the Registrant's Current Report on Form 8-K filed with the SEC on September 11, 2023).
4.25	Form of Replacement Warrant issued in February 2024 Warrant Inducement Transaction (Incorporated by reference to Exhibit 4.01 to the Registrant's Current Report on Form 8-K filed with the SEC on February 1, 2024).
4.26	Form of Placement Agent Warrant issued in February 2024 Warrant Inducement Transaction (Incorporated by reference to Exhibit 4.02 to the Registrant's Current Report on Form 8-K filed with the SEC on February 1, 2024).
4.27	Form of Common Stock Warrant issued in May 2024 Private Placement (Incorporated by reference to Exhibit 4.02 to the Registrant's Current Report on Form 8-K filed with the SEC on May 3, 2024).
4.28	Form of Placement Agent Warrant issued in May 2024 Private Placement (Incorporated by reference to Exhibit 4.03 to the Registrant's Current Report on Form 8-K filed with the SEC on May 3, 2024).
4.29	Form of Five-Year Common Stock Purchase Warrant issued in December 2024 Underwritten Public Offering (Incorporated by reference to Exhibit 1.01 to the Registrant's Current Report on Form 8-K filed with the SEC on December 16, 2024).
4.30	Form of July 2025 New Warrant (Incorporated by reference to Exhibit 4.01 to the Registrant's Current Report on Form 8-K filed with the SEC on July 25, 2025).

4.31	Form of July 2025 Placement Agent Warrant (Incorporated by reference to Exhibit 4.02 to the Registrant's Current Report on Form 8-K filed with the SEC on July 25, 2025).
4.32	Form of July 2025 Warrant Inducement Agreement (Incorporated by reference to Exhibit 10.01 to the Registrant's Current Report on Form 8-K filed with the SEC on July 25, 2025).
4.33	Form of Pre-Funded Warrant (Incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-290568), filed with the SEC on September 29, 2025).
4.34	Form of Representative Warrant (Incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-290568), filed with the SEC on September 29, 2025).
4.35	Form of Warrant Agency Agreement (Incorporated by reference to Exhibit 4.3 to the Registrant's Registration Statement on Form S-1 (File No. 333-290568), filed with the SEC on September 29, 2025).
10.1[#]	License Agreement, by and between Leading BioSciences, Inc. and The Regents of the University of California, dated August 19, 2015, as amended on December 20, 2019 (Incorporated by reference to Exhibit 10.18 to the Registrant's Registration Statement on Form S-4 (File No. 333-251659), originally filed with the SEC on December 23, 2020, as amended).
10.2[#]	License Agreement, by and between Leading BioSciences, Inc. and The Regents of the University of California, dated April 1, 2020 (Incorporated by reference to Exhibit 10.19 to the Registrant's Registration Statement on Form S-4 (File No. 333-251659), originally filed with the SEC on December 23, 2020, as amended).
10.3[#]	License Agreement, by and between Palisade Bio, Inc. and The Regents of the University of California, dated July 30, 2021 (incorporated by reference to Exhibit 10.5 to the Registrant's Form 10-K, filed with the SEC on March 17, 2022).
10.4[#]	Co-Development and Distribution Agreement, by and between Leading BioSciences, Inc. and Newsoara Biopharma Co., Ltd. (as successor-in-interest to Biolead Medical Technology Limited), dated February 17, 2018, as amended on November 27, 2018 (Incorporated by reference to Exhibit 10.20 to the Registrant's Registration Statement on Form S-4 (File No. 333-251659), originally filed with the SEC on December 23, 2020, as amended).
10.5[†]	Securities Purchase Agreement, by and between Leading BioSciences, Inc. and the investor party thereto, dated December 16, 2020 (Incorporated by reference to Exhibit 10.5 to the Registrant's Current Report on Form 8-K, filed with the SEC on December 21, 2020).
10.6[†]	Securities Purchase Agreement, by and among Seneca Biopharma, Inc., Leading BioSciences, Inc. and the investor party thereto, dated December 16, 2020 (Incorporated by reference to Exhibit 10.6 to the Registrant's Current Report on Form 8-K, filed with the SEC on December 21, 2020).
10.7	Amendment Agreement to Securities Purchase Agreement by and among, the Company, Leading BioSciences, Inc. and Altium Growth Fund, LP, dated May 3, 2021 (Incorporated by reference to Exhibit 10.03 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on May 14, 2021).
10.8[+]	Leading BioSciences, Inc. Amended and Restated 2013 Employee, Director and Consultant Equity Incentive Plan and Forms of Stock Option Grant Notice, Stock Option Agreement and Notice of Exercise of Stock Option thereunder (Incorporated by reference to Exhibit 10.24 to the Registrant's Registration Statement on Form S-4 (File No. 333-251659), originally filed with the SEC on December 23, 2020, as amended).
10.9[+]	Palisade Bio, Inc. 2021 Equity Incentive Plan, as amended (Incorporated by reference to Exhibit 10.01 to the Registrant's Current Report on Form 8-K, filed with the SEC on June 9, 2023).
10.10[+]	Form of Stock Option Grant Notice, Stock Option Agreement and Notice of Exercise under the Palisade Bio, Inc. 2021 Equity Incentive Plan (Incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K, filed with the SEC on November 23, 2021).
10.11[+]	Form of Non-Employee Director Stock Option Grant Notice, Stock Option Agreement and Notice of Exercise under the Palisade Bio, Inc. 2021 Equity Incentive Plan (Incorporated by reference to Exhibit 10.5 to the Registrant's Current Report on Form 8-K, filed with the SEC on November 23, 2021).

10.12[+]	Form of Restricted Stock Unit Grant Notice and Award Agreement under the Palisade Bio, Inc. 2021 Equity Incentive Plan (Incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on November 10, 2025).
10.13[+]	Form of Restricted Stock Unit Grant Notice and Award Agreement under the Palisade Bio, Inc. 2021 Equity Incentive Plan (Optional Cash Settlement) (Incorporated by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on November 10, 2025).
10.14[+]	Palisade Bio, Inc. Employee Stock Purchase Plan (Incorporated by reference to Exhibit 10.02 to the Registrant's Current Report on Form 8-K, filed with the SEC on June 9, 2023).
10.15[+]	Palisade Bio, Inc. 2021 Inducement Incentive Plan, as Amended August 7, 2023 (Incorporated by reference to Exhibit 10.20 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on August 10, 2023).
10.16[+]	Form of Restricted Stock Unit Grant Notice and Award Agreement under the Palisade Bio, Inc. 2021 Inducement Incentive Plan (Incorporated by reference to Exhibit 99.1 to the Registrant's Registration Statement on Form S-8 (File No. 333-261196), filed with the SEC on November 19, 2021).
10.17[+]	Form of Stock Option Grant Notice and Award Agreement under the Palisade Bio, Inc. 2021 Inducement Incentive Plan (Incorporated by reference to Exhibit 99.2 to the Registrant's Registration Statement on Form S-8 (File No. 333-261196), filed with the SEC on November 19, 2021).
10.18[+]	Non-Employee Director Compensation Policy (Incorporated by reference to Exhibit 10.35 to the Registrant's Annual Report on Form 10-K filed with the SEC on March 22, 2023).
10.19[†]	Asset Transfer Agreement, by and between Alto Neuroscience, Inc. and Palisade Bio, Inc., dated October 18, 2021 (incorporated by reference to Exhibit 10.27 to the Registrant's Form 10-K, filed with the SEC on March 17, 2022).
10.20	Form of Securities Purchase Agreement, dated May 6, 2022, by and among the Company and the purchasers named therein (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on May 6, 2022).
10.21	Form of Securities Purchase Agreement dated December 30, 2022, by and among the Company and the purchasers named therein (Incorporated by Reference to Exhibit 10.01 to the Registrant's Current report on Form 8-K, filed with the SEC on January 4, 2023).
10.22	Form of Registration Rights Agreement by and among the Company and signatories named therein (Incorporated by reference to Exhibit 10.02 to the Registrant's Current Report on Form 8-K, filed with the SEC on January 4, 2023).
10.23	Form of Placement Agency Agreement, dated December 30, 2022, by and between the Company and Ladenburg Thalmann & Co Inc. (Incorporated by reference to Exhibit 10.03 to the Registrant's Current Report on Form 8-K, filed with the SEC on January 4, 2023).
10.24	Form of Securities Purchase Agreement dated April 3, 2023, by and among the Company and the purchasers named therein (Incorporated by Reference to Exhibit 10.01 to the Registrant's Current Report on Form 8-K, filed with the SEC on April 5, 2023).
10.25	Form of Registration Rights Agreement dated by and among the Company and the signatories named therein (Incorporated by Reference to Exhibit 10.02 to the Registrant's Current Report on Form 8-K, filed with the SEC on April 5, 2023).
10.26	Form of Placement Agency Agreement by and among the Company and Ladenburg Thalmann & Co Inc. (Incorporated by Reference to Exhibit 10.01 to the Registrant's Current Report on Form 8-K, filed with the SEC on April 5, 2023).
10.27[#]	Form of Research, Collaboration, and License Agreement with Giiant Pharma (Incorporated by reference to Exhibit 10.01 to the Registrant's Current Report on Form 8-K, filed with the SEC on September 8, 2023.
10.28	Form of Securities Purchase Agreement dated September 7, 2023, by and among the Company and the signatories named therein (Incorporated by Reference to Exhibit 10.01 to the Registrant's Current report on Form 8-K, filed with the SEC on September 11, 2023).

10.29	Form of Placement Agency Agreement dated September 7, 2023, by and among the Company and Ladenburg Thalmann & Co Inc. (Incorporated by reference to Exhibit 10.02 to the Registrant's Current Report on Form 8-K, filed with the SEC on September 11, 2023).
10.30	Form of Warrant Inducement Agreement entered into pursuant to February 2024 Warrant Inducement Transaction (Incorporated by reference to Exhibit 10.01 to the Registrant's Current Report on Form 8-K, filed with the SEC on February 1, 2024).
10.31	Form of Securities Purchase Agreement entered into pursuant to the May 2024 Private Placement (Incorporated by reference to Exhibit 10.01 to the Registrant's Current Report on Form 8-K, filed with the SEC on May 3, 2024).
10.32	Form of Registration Right Agreement entered into Pursuant to the May 2024 Private Placement (Incorporated by reference to Exhibit 10.02 to the Registrant's Current Report on Form 8-K, filed with the SEC on May 3, 2024).
10.34	Form of Placement Agency Agreement entered into Pursuant to the May 2024 Private Placement (Incorporated by reference to Exhibit 10.03 to the Registrant's Current Report on Form 8-K, filed with the SEC on May 3, 2024.
10.34#	Amendment to Research Collaboration and License Agreement with Giiant Pharma, Inc. dated August 2, 2024 (Incorporated by reference to Exhibit 10.48 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on August 12, 2024).
10.35	Form of Warrant Amendment Agreement entered into Pursuant to the December 2024 Underwritten Public Offering (Incorporated by reference to Exhibit 1.01 to the Registrant's Current Report on Form 8-K filed with the SEC on December 16, 2024).
10.36+	Amended and Restated Employment Agreement with J.D. Finley, dated September 4, 2025 (Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on November 10, 2025).
10.37+	Amended and Restated Employment Agreement with Mitchell Jones, dated September 4, 2025 (Incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on November 10, 2025).
19.1	Registrant's Insider Trading Policy (Incorporated by reference to Exhibit 19.1 to the Registrant's Registration Statement on Form S-1, filed with the SEC on October 30, 2024).
21.1	Subsidiaries of Registrant (Incorporated by reference to Exhibit 21.1 to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 22, 2023).
23.1*	Consent of Baker Tilly US, LLP, Independent Registered Public Accounting Firm
31.1*	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Exchange Act.
31.2*	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Exchange Act.
32.1**	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rules 13a-14(b) or 15d-14(b) of the Exchange Act, and 18 U.S.C. Section 1350.
97.1	Clawback Policy of the Registrant (Incorporated by reference to Exhibit 97.1 to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 26, 2024).
101.INS*	Inline XBRL Instance Document-the instance document does not appear in the Interactive Data File as its XBRL tags are embedded within the Inline XBRL document.
104*	Cover Page Interactive Data File (embedded within the Inline XBRL and contained in Exhibit 101).

* Filed herewith
** Furnished herewith.
+ Indicates management contract or compensatory plan.
# Certain portions of this exhibit (indicated by "[***]") have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

† Schedules and exhibits to the Agreement have been omitted pursuant to Item 601(a)(5) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the Securities and Exchange Commission upon request.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

PALISADE BIO, INC.

Date: March 20, 2026

By: /s/ J.D. Finley
J.D. Finley
Chief Executive Officer,
Chief Financial Officer and Director

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints J.D. Finley, as his or her true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him or her and in his or her name, place, and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming that said attorney-in-fact and agent, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ J.D. Finley **J.D. Finley**	Chief Executive Officer, Chief Financial Officer and Director (Principal Executive and Financial Officer)	March 20, 2026
/s/ Mitchell Jones, M.D., Ph.D. **Mitchell Jones, M.D., Ph.D.**	President and Chief Medical Officer	March 20, 2026
/s/ Donald A. Williams **Donald A. Williams**	Chairman of the Board of Directors	March 20, 2026
/s/ Emil Chuang **Emil Chuang**	Director	March 20, 2026
/s/ Binxian Wei **Binxian Wei**	Director	March 20, 2026

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